

Strategies for Managing Dual Use Research of Concern in Life Sciences

Murray L. Cohen, PhD, MPH, CIH

55th ABSA Annual Conference

Orlando, Florida

October 23, 2012

Background

- **November 2011**, NSABB recommended publication of 2 NIH-funded studies of H5N1 transmissibility and pathogenesis in ferrets in a redacted form
- **November/December**, journal editors raised concerns about how to control the access to certain research information and products and suggested a controlled access mechanism be developed
- **December**, establishment of NSABB Working Group on Global Engagement for DURC
- **February 2012**, everybody's hair was on fire...

Attributes of H5N1 DURC that may Warrant Restricted Communication

1. The research results in the generation of highly transmissible, highly pathogenic viral strains that pose the risk of substantial harm to large populations of mammals or other animals.
2. The timeframe for the risk of harm is the near-term.
3. Countermeasures are either unavailable or limited in efficacy, availability, or sustainability.
4. Misuse of the research information, technologies, or products would require both (a) little or no additional information and (b) readily accessible levels of expertise, technology, and/or material (i.e., “enabling.”)

“SCARED YET?!”

-- Mark Denison, 22 Oct 12

- Mechanisms of trans-species zoonotic virus movement and adaptation are unknown
- Delays in response can be devastating
- Rare events that are hard for the virus; that's why we're still here.

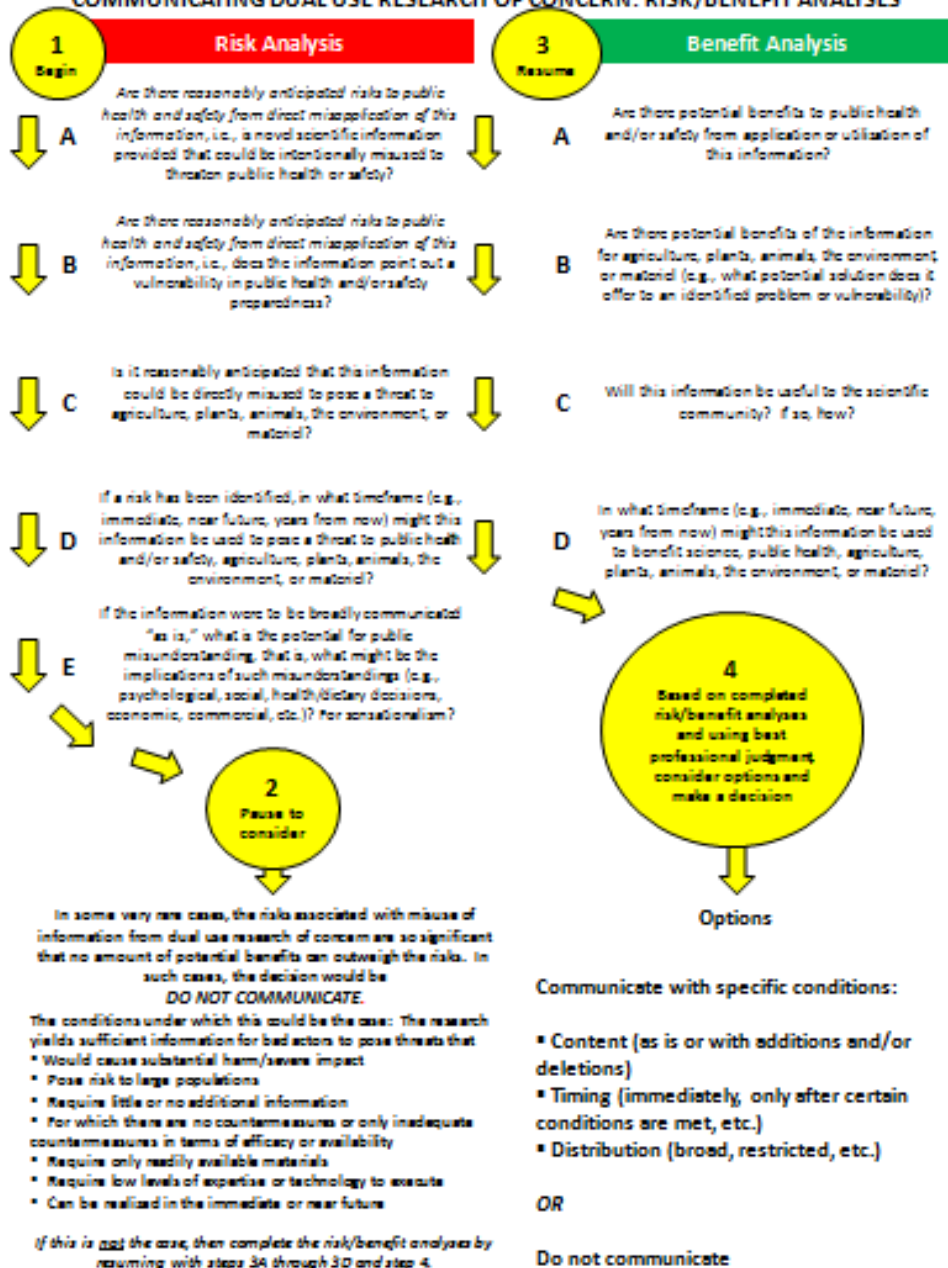
Swift USG Response, BUT...

“Discouraging researchers or institutions from federally funded research with select agents,
Or delaying research with additional layers of review can only hurt national security.”

Carrie D. Wolinetz, AAU

Science Policy Forum, Feb 2012

COMMUNICATING DUAL USE RESEARCH OF CONCERN: RISK/BENEFIT ANALYSES



Communicating Dual Use Research of Concern: A Process Map for Risk/Benefit Analyses

The WHO self-assessment questionnaire on Responsible life sciences research

- Self-assessment tool provides important insights into research, ethics and laboratory biosafety and biosecurity (e.g. mapping, strengths, gaps in knowledge and weaknesses)
- It contributes to the identification of priority areas for action (e.g. what is needed and for whom?)
- It is flexible tool and could be reproduced elsewhere

OOPS!!!

“The government is a big operation. At any given time something screws up...

You find out what’s broken and you fix it.”

-- President Obama,
18 October 2012

“Don’t screw up!”

-- Murray Cohen

23 October 2012

Take DURC Seriously

Don't be scared

- Put Policies/procedures in place
- Part and parcel of Research Integrity, protection of the research enterprise. DURC is NOT a negative categorization.
- Control at the Institutional Level
- Utilize available tools and resources
- Consider DURC potential in early stages of research conceptualization
- Oversight throughout the course of the identified research projects in order to consider alternative approaches

Some Useful Resources

- www.who.int
- NSABB(http://oba.od.nih.gov/biosecurity/biosecurity_educational.html).
- <http://cstsp.aaas.org/content.html?contentid=2533>

Bridging Science and Security for Biological Research: A Discussion about Dual Use Research Review and Oversight at Research Institutions