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European Research Infrastructure
on Highly Pathogenic Agents

RDA
RESEARCH DATA ALLIANCE

Some thoughts on
What are sensitive data ?

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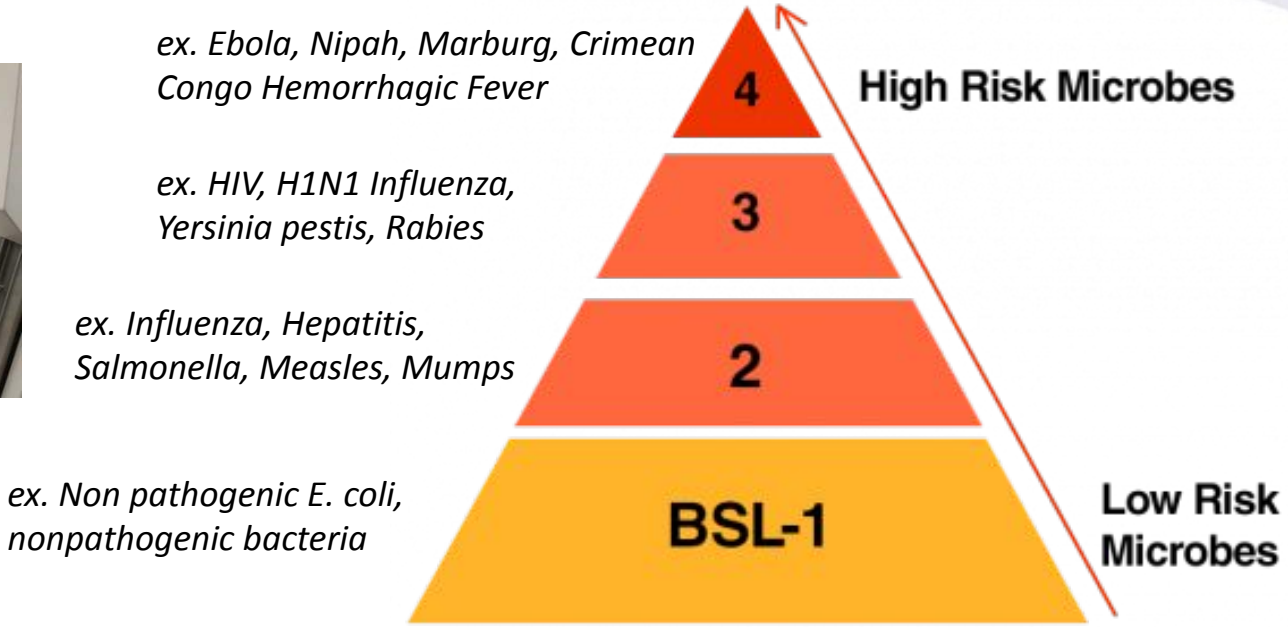
RDA Sensitive Data IG

vRDA P17, University of Edinburgh, 21 april 2021

ERINHA is a RI of biocontainment laboratories which is specialized in infectious disease research

BSL-4

BSL-3



Biocontainment laboratories:

- **Unique buildings with complex engineering systems maintaining 'containment'**
- **Increased personnel and information security**
- **Nationally and internationally regulated**

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Sensitive data: main types

4 points considering possible community “Risks”

- Economical risks
- Interference with security programs / tools
- Misappropriation of knowledge and data (for instance to build a weapon)
- Terrorism (plan and access to hospital, stadium…)

Environmental sensitive data

- Endangering coveted and scarce resources (including relocalisable data)

Personal data

- Endangering pearson (including re-identifiable data)

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Sensitive data within biocontainment laboratories

Type of Data	Examples	Protected?
Building Information	Equipment location; IT network controlling equipment; Type of decontamination;	Yes; institution specific
Personnel	Names; knowledge; access to facility	Yes; institution specific
Inventory	Quantity, quality, and location of pathogens stored in laboratory	Yes; institution specific; required (by international treaty) to be protected
Procedures and Scientific Methods	How are pathogens handled?	Depends. Methods may be published
Data and Results	Data generated by experimentation	Depends. Data and results may be published

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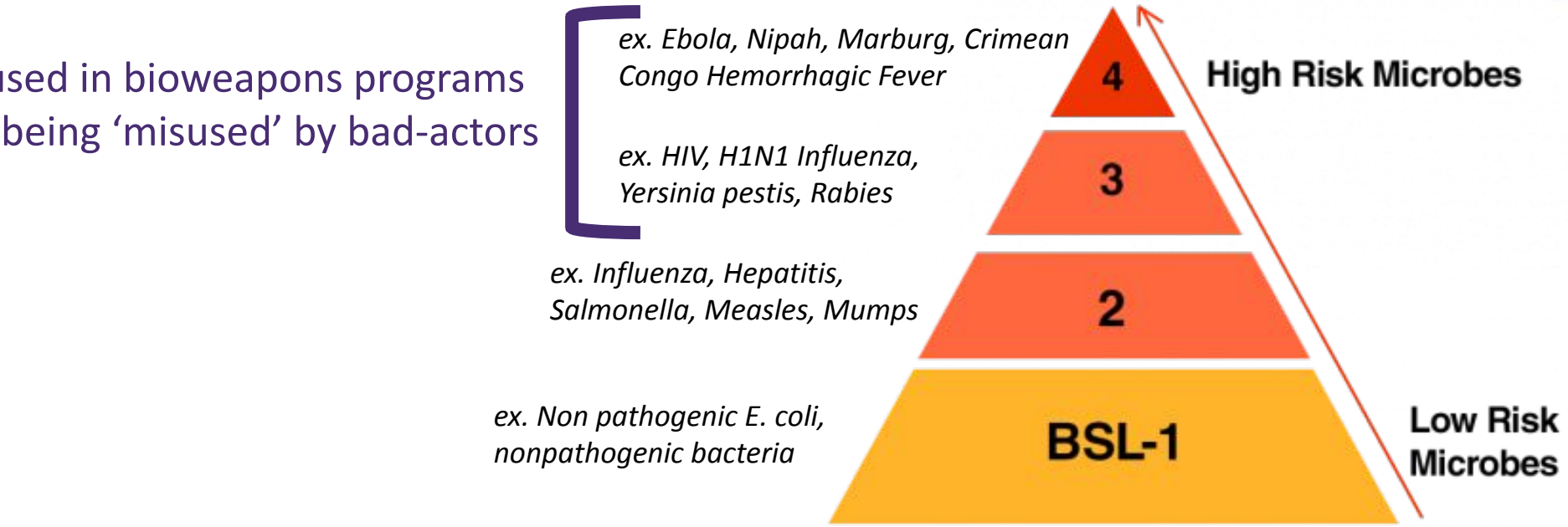
This data comprises National Security Data and should never be required to be shared in an open-access manner.

Methods/Procedures and Results

- Previously used in bioweapons programs
- High risk of being ‘misused’ by bad-actors



How do we prevent the procedures and data generated within these laboratories from being used maliciously?

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Dual use research of concern (DURC)

Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies

- **that could be directly misapplied to pose a significant threat, with broad potential consequences, to**
  - public health and safety,
  - agricultural crops and other plants,
  - animals,
  - the environment,
  - materiel, or
  - national security.

**As defined by the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*

Types of research that may trigger DURC concerns

Taken from WHO Informal Consultation on Dual Use Research of Concern (2013)

- Demonstrate how to render a vaccine ineffective
- Enhance the harmful consequences of a pathogen or toxin or render a non-pathogen virulent
- Increase the transmissibility of a pathogen
- Alter the host range of a pathogen or toxin
- Enable evasion of diagnostic or detection modalities
- Enhance the susceptibility of a host population to a pathogen or toxin
- Generate or reconstitute certain eradicated or extinct pathogens or toxins
- Enable weaponization of a biological agent or toxin.

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Examples of DURC data

- Demonstrate how to render a vaccine ineffective

JOURNAL OF VIROLOGY, Feb. 2001, p. 1205–1210 Vol. 75, No. 3
0022-538X/01/$04.00+0 DOI: 10.1128/JVI.75.3.1205–1210.2001

Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

RONALD J. JACKSON,[1,2*] ALISTAIR J. RAMSAY,[2†] CARINA D. CHRISTENSEN,[2] SANDRA BEATON,[1] DIANA F. HALL,[1‡] AND IAN A. RAMSHAW[2]

Pest Animal Control Cooperative Research Centre, CSIRO Sustainable Ecosystems,[1] and Division of Immunology and Cell Biology, John Curtin School of Medical Research, Australian National University,[2] Canberra, Australia

Received 25 July 2000/Accepted 13 November 2000

The IL-4 recombinant mousepox virus was lethal to all mice, including those previously vaccinated against mousepox. Potential to be used on other poxviruses

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Examples of DURC data

- Increase the transmissibility of a pathogen

Published in final edited form as:
Science. 2012 June 22; 336(6088): 1534–1541. doi:10.1126/science.1213362.

Science
AAAS

Airborne Transmission of Influenza A/H5N1 Virus Between Ferrets

Sander Herfst[1], **Eefje J. A. Schrauwen**[1], **Martin Linster**[1], **Salin Chutinimitkul**[1], **Emmie de Wit**[1], **Vincent J. Munster**[1], **Erin M. Sorrell**[1], **Theo M. Bestebroer**[1], **David F. Burke**[2], **Derek J. Smith**[1,2,3], **Guus F. Rimmelzwaan**[1], **Albert D. M. E. Osterhaus**[1], and **Ron A. M. Fouchier**[1,†]

[1]Department of Virology, Erasmus Medical Center, Rotterdam, The Netherlands [2]Department of Zoology, University of Cambridge, Cambridge, UK [3]Fogarty International Center, National Institutes of Health (NIH), Bethesda, MD 20892, USA

Created a influenza A virus with increased transmissibility

nature
International journal of science

LETTER

doi:10.1038/nature10831

Experimental adaptation of an influenza H5 HA confers respiratory droplet transmission to a reassortant H5 HA/H1N1 virus in ferrets

Masaki Imai[1], Tokiko Watanabe[1,2], Masato Hatta[1], Subash C. Das[1], Makoto Ozawa[1,3], Kyoko Shinya[4], Gongxun Zhong[1], Anthony Hanson[1], Hiroaki Katsura[5], Shinji Watanabe[1,2], Chengjun Li[1], Eiryo Kawakami[2], Shinya Yamada[5], Maki Kiso[5], Yasuo Suzuki[6], Eileen A. Maher[1], Gabriele Neumann[1] & Yoshihiro Kawaoka[1,2,3,5]

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Examples of DURC data

- Enhance the harmful consequences of a pathogen or toxin or render a non-pathogen virulent
- Confer resistance to antibiotics, antiviral agents, or anti-toxins

A Novel Strain of *Clostridium botulinum* That Produces Type B and Type H Botulinum Toxins

Jason R. Barash and Stephen S. Arnon

Infant Botulism Treatment and Prevention Program, California Department of Public Health, Richmond, California

Scientists identified a new C. botulinum toxin that could not be neutralized by known countermeasures. The journal allowed publication but withheld the sequence of the toxin (until a countermeasure is developed)

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Examples of DURC data

- Generate or reconstitute certain eradicated or extinct pathogens or toxins

Science
AAAS

Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus
Terrence M. Tumpey, *et al.*
Science **310**, 77 (2005);
DOI: 10.1126/science.1119392

PLOS ONE

RESEARCH ARTICLE

Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments

Ryan S. Noyce[1], Seth Lederman[2], David H. Evans[1]*

1 Department of Medical Microbiology & Immunology and Li Ka Shing Institute of Virology, University of Alberta, Edmonton, Alberta, Canada, **2** Tonix Pharmaceuticals, Inc., New York, New York, United States of America

Both studies reconstitute viruses that are not known to be circulating and have previously caused devastating epidemics

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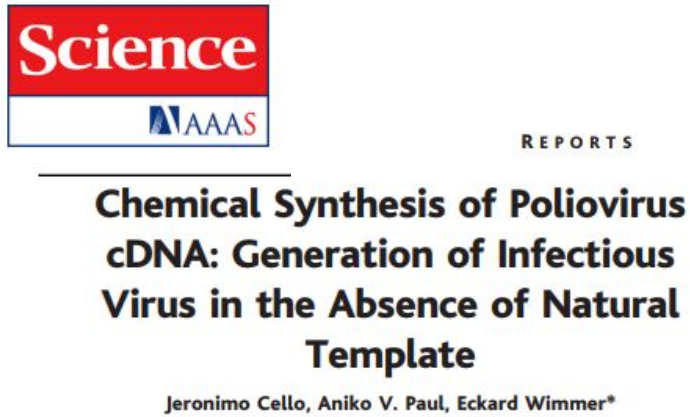
Examples of DURC data

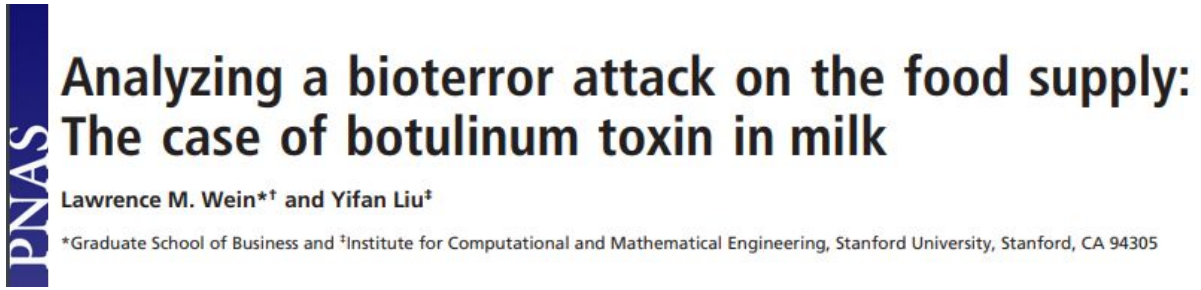
- Enable weaponization of a biological agent or toxin.


Science
AAAS

REPORTS

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

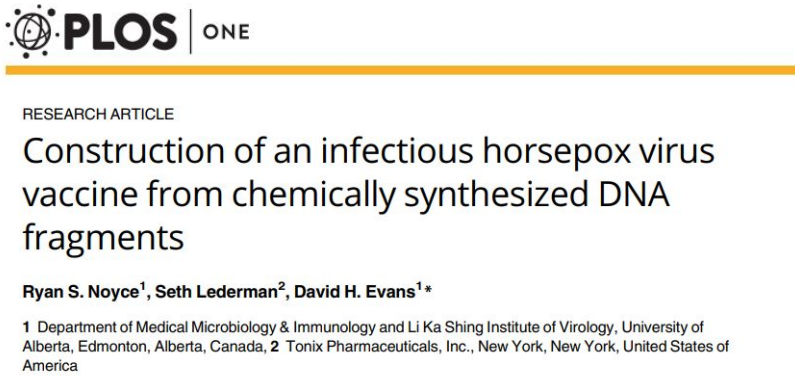
Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*


PNAS

Analyzing a bioterror attack on the food supply: The case of botulinum toxin in milk

Lawrence M. Wein*† and Yifan Liu‡

*Graduate School of Business and ‡Institute for Computational and Mathematical Engineering, Stanford University, Stanford, CA 94305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Publishes methods on creating agents closely related to known WMD agents

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DURC DATA are NOT BAD DATA

Scientific advances are necessary for development of vaccines, therapeutics, diagnostics and to further scientific knowledge

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Questions?

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