Why there is a “gray area” and why we need new approaches for managing it

David A. Relman, Stanford University

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A brief history: 'dual use' research…

- The Cold War; nuclear weapons paradigm; moral dilemmas
- 1982 NAS: *Scientific Communication & National Security*, "Corson Report" –bright line?, "gray zone"
- 1985 Reagan: NSDD-189 "to maximum extent possible, products of fundamental research remain unrestricted…where national security requires control, mechanism…is classification"
- Ongoing revolution in life sciences….and 9/11, anthrax
- 2004 NRC *Biotechnology Research in an Age of* Terrorism
- 2005 National Science Advisory Board on Biosecurity
- 2006 NRC, *Globalization, Biosecurity, and the Future of the Life Sciences*
- 2011 NSABB *Recommendations on Communication of Experimental Adaptation of Avian Influenza A/H5N1*

A bright line between

The Panel found it possible to define three categories of university research. The first, and by far the largest share, are those activities in which the benefits of total openness overshadow their possible near-term military benefits to the Soviet Union. There are also those areas of research for which classification is clearly indicated. Between the two lies a a small "gray area" of research activities for which limited restrictions short of classification are appropriate.

The Panel's criteria leave narrow gray areas for which, in a few instances, limited restrictions short of classification are appropriate. An example of such a gray area may be a situation, anticipated in large-scale integrated circuit work, in which on-campus research merges directly into process technology with possible military application. In its recommendations the Panel has formulated provisions that might be applicable to such a situation.

NATIONAL ACADEMY PRESS
Washington, D.C. 1982

1982

Why there is 'gray', why it won't go away, why it needs serious attention

- Inherent, pervasive applicability of basic science, blurring of line
- Unanticipated findings
- Problems with classification: burdens, limited applicability (owned, controlled, produced by/for USG*)
- Ongoing revolution in life sciences: growing consequences/risks (natural vs. manipulations)
- Ogburn (1922): 'cultural lag' leading to delayed recognition/informed consent
- Social/moral contract with rest of public

* Executive Office of the President of the United States. Executive Order 12958. Classified national security information. Vol. 60. Washington, DC: Federal Register, 1995:19825–43.

Defining 'Gray'

Corson: Four criteria to define research for which communication ought to be limited (all must be met)

(1) research with dual use or military applications;

(2) research with short time to such applications;

(3) research when dissemination could give short-term advantage to adversaries; and

(4) research when information is believed not to be already held by adversaries

Dealing With 'Gray'

- Post-hoc national security classification?
- Non-classification control by government?
- Voluntary control by investigator?
- Time-limited measures
- No control?: "inherent limits on the feasibility and effectiveness of controls"

A messy case study....

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

(See the major article by Dover et al on pages 192–202, and the editorial commentaries by Popoff on pages 168–9 and Hooper and Hirsch on page 167 and Relman on pages 170–2.)

Background. *Clostridium botulinum* strain IBCA10-7060, isolated from a patient with infant botulism, produced botulinum neurotoxin type B (BoNT/B) and another BoNT that, by use of the standard mouse bioassay, could not be neutralized by any of the Centers for Disease Control and Prevention–provided monovalent polyclonal botulinum antitoxins raised against BoNT types A–G.

Methods and Results. The combining of antitoxins to neutralize the toxicity of known bivalent *C. botulinum* strains Ab, Ba, Af, and Bf also failed to neutralize the second BoNT. Analysis of culture filtrate by double immunodiffusion yielded a single line of immunoprecipitate with anti-A, anti-B, and anti-F botulinum antitoxins but not with anti-E antitoxin. A heptavalent $F(ab')_2$ botulinum antitoxin A–G obtained from the US Army also did not neutralize the second BoNT. An antitoxin raised against IBCA10-7060 toxoid protected mice against BoNT/B (Okra) and against the second BoNT but did not protect mice against BoNT/A (Hall) or BoNT/F (Langeland).

Conclusion. The second BoNT thus fulfilled classic criteria for being designated BoNT/H. IBCA10-7060 is the first *C. botulinum* type Bh strain to be identified. BoNT/H is the first new botulinum toxin type to be recognized in >40 years, and its recognition could not have been accomplished without the availability of the mouse bioassay.

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Botulinum Toxin as a Biological Weapon

Medical and Public Health Management

Stephen S. Arnon, MD

Robert Schechter, MD

Thomas V. Inglesby, MD

[illegible], MD

[illegible], MD

[illegible], MD

Edward Eitzen, MD, MPH

Anne D. Fine, MD

Jerome Hauer, MPH

Marcelle Layton, MD

Scott Lillibridge, MD

Michael T. Osterholm, PhD, MPH

Tara O'Toole, MD, MPH

Gerald Parker, PhD, DVM

Trish M. Perl, MD, MSc

Philip K. Russell, MD

David L. Swerdlow, MD

Kevin Tonat, PhD, MPH

for the Working Group on Civilian Biodefense

>$500 million for anti-BoNT antisera in SNS

Objective The Working Group on Civilian Biodefense has developed consensus-based recommendations for measures to be taken by medical and public health professionals if botulinum toxin is used as a biological weapon against a civilian population.

Participants The working group included 23 representatives from academic, gov-

[illegible]

MEDLINE (1960–March 1999) and their professional collections for literature concerning use of botulinum toxin as a bioweapon. The literature was reviewed, and opinions were sought from the working group and other experts on diagnosis and management of botulism. Additional MEDLINE searches were conducted through April 2000 during the review and revisions of the consensus statement.

Consensus Process The first draft of the working group's consensus statement was a synthesis of information obtained in the formal evidence-gathering process. The working group convened to review the first draft in May 1999. Working group members reviewed subsequent drafts and suggested additional revisions. The final statement incorporates all relevant evidence obtained in the literature search in conjunction with final consensus recommendations supported by all working group members.

Conclusions An aerosolized or foodborne botulinum toxin weapon would cause acute symmetric, descending flaccid paralysis with prominent bulbar palsies such as diplopia, dysarthria, dysphonia, and dysphagia that would typically present 12 to 72 hours after exposure. Effective response to a deliberate release of botulinum toxin will depend on timely clinical diagnosis, case reporting, and epidemiological investigation. Persons potentially exposed to botulinum toxin should be closely observed, and those with signs of botulism require prompt treatment with antitoxin and supportive care that may include assisted ventilation for weeks or months. Treatment with antitoxin should not be delayed for microbiological testing.

JAMA. 2001;285:1059-1070 www.jama.com

Fall 2010, from AQAP

These are some of our suggestions. The best operation however is the one where you come up with an innovative idea that the authorities have not yet turned their attention to, and that leads to maximum casualties or – equally important – maximum economic losses. Also those brothers of ours who have specialized expertise and those who work in sensitive locations that would offer them unique opportunities to wreak havoc on the enemies of Allah should take advantage of their skills.

For those mujahid brothers with degrees in microbiology or chemistry lays the greatest opportunity and responsibility. For such brothers we encourage them to develop a weapon of mass destruction, i.e., an effective poison with the proper method of delivery.

Poisonous gases such as nerve gas are not out of reach for the chemist and require simple equipment. A microbiologist would be capable of developing the most effective strains of Clostridium botulinum and thus develop the most lethal toxin of all: botulin. An effective botulin attack administered properly could lead to hundreds if not thousands of casualties.

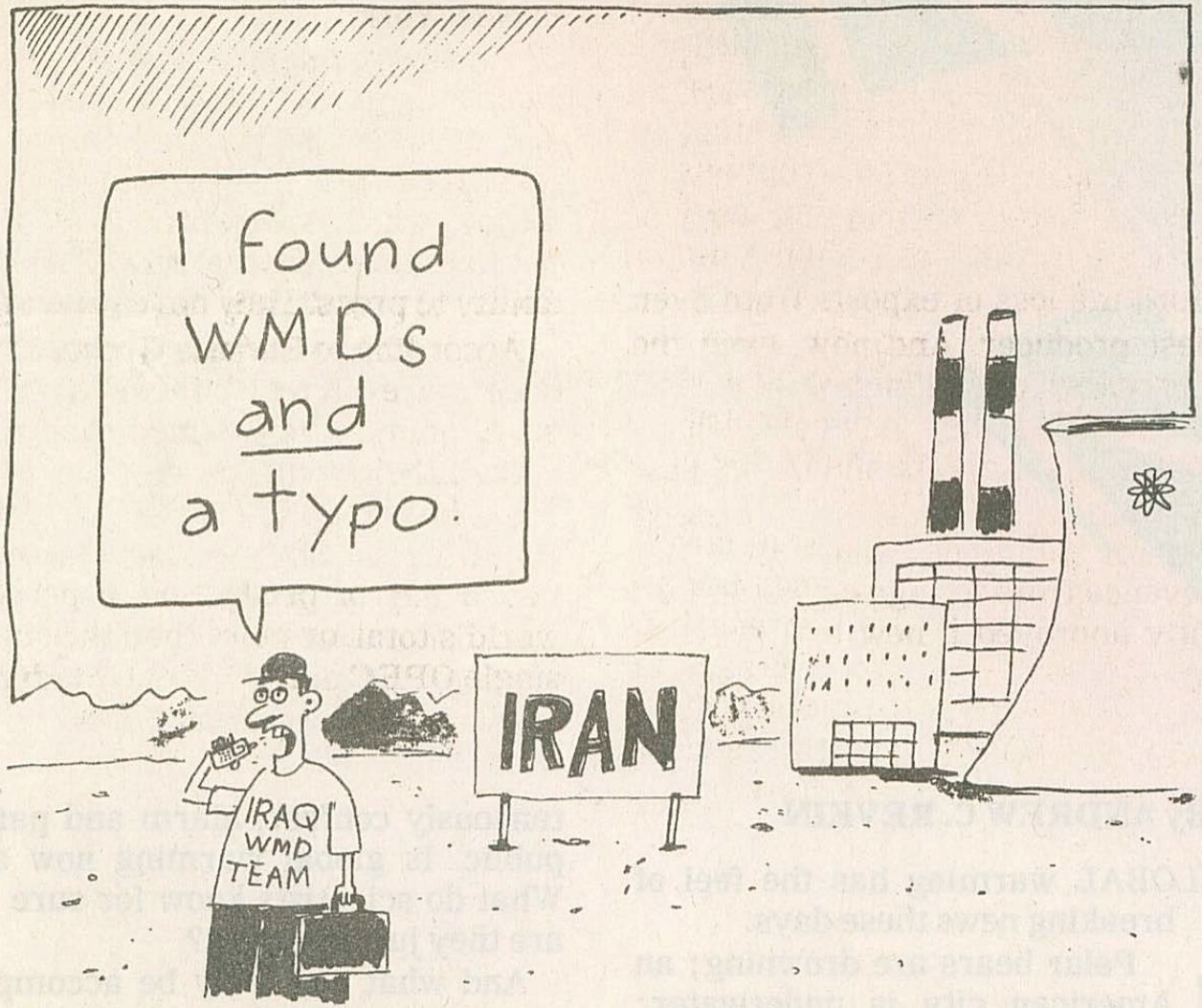
For such brothers we would ask them to take the utmost security precautions and take their time even if that means years. Such an operation is worth the wait.

Brothers with less experience in the fields of microbiology or chemistry as long as they posses basic scientific knowledge would be able to develop other poisons such as ricin or cyanide.

Due to the extreme importance of moving the war with America over to the next stage, the stage of weapons of mass destruction, we will In Shā' Allāh cover such topics in more detail in our upcoming issues. Until then may Allah protect you all and guide you to what is best for you in this life and the afterlife.

Events surrounding Arnon

- 2012--Private meeting of USG experts: "publish"
- Arnon argues for withholding of sequence information; NSABB: no comment; JID accedes to request...2013 Publications
- Public criticism: arbitrariness, ad hoc, hindered validation of science. CA DPH intervenes...Arnon muzzled



Gary Clement
National Post (Canada)

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- Public criticism: arbitrariness, ad hoc, hindered validation of science. CA DPH intervenes...Arnon muzzled
- CDC obtains strain->BEI->FDA: seq/pub (!)
- Anti-BoNT/H MAbs developed (JID, 2016)

EDITORIAL COMMENTARY

"Inconvenient Truths" in the Pursuit of Scientific Knowledge and Public Health

David A. Relman[1,2,3,4]

[1]Department of Medicine, [2]Department of Microbiology and Immunology, and [3]Center for International Security and Cooperation, Stanford University; and [4]Veterans Affairs Palo Alto Health Care System, California

(See the major article by Barash and Arnon on pages 183–91 and Dover et al on pages 192–202, and the editorial commentaries by Popoff on pages 168–9 and Hooper and Hirsch on page 167.)

Lessons:

Inadequate discussion of risks, benefits, opaqueness of process

Role of individual investigators?

Decisions to control dissemination of information require widely-accepted process, coordination, oversight

J Infect Dis 2014;209:170-172

Science and Morality: 'Doing the right thing'

- Modern science, in general, demands consideration of morality because of blurred line between basic & applied science
- "Justice involves cultivating virtue and reasoning about the common good" (Sandel, *Justice*, 2009)
- "I'm not asking scientists to sacrifice their careers, but just to spend a little bit of time thinking about the consequences of their work. Science is playing an increasingly important role in the whole future of mankind" (Joseph Rotblat, on leaving Bomb Project)
- Scientists have social obligations that involve more than blind pursuit of information ("Social Contract")

Conclusions-1

- There is small, but growing gray area; work in this area is increasingly consequential. Risks are assumed before benefits are realized.
- Society is inadequately served by just 2 options, i.e., unrestricted dissemination and classification
- Classified life sciences research: (besides burden, applicability)…coordination?, oversight?, review?, sharing?

Conclusions-2

- Mechanism(s) for short-term, limited distribution are needed while risk mitigation measures are created/deployed; national system? gray area org?
- Scientists have moral and social responsibilities in flagging risks; national security experts have responsibilities in communicating threats; informed consent of public is required
- Process & mechanism(s) need to be transparent, deliberative, inclusive