NCID/CDC Biodefense Research: Priorities and Funding Opportunities

Mary L. Lerchen, DrPH, MS
Acting Director, Office of Extramural Research
National Center for Infectious Diseases (NCID)
Centers for Disease Control and Prevention
Health and Human Services
Purpose

- To describe the changing research environment at CDC
- To describe the changing world environment that is influencing extramural research
- To describe how NCID/CDC is responding by supporting bioterrorism preparedness research activities
Funding Opportunities

• Announced in collaboration with NIH NIAID
  – Award FY03 $9 M
  – Award FY04 $9 M (application receipt date 6/1/03)
• Separate NCID CDC announcement complimentary to NIH NIAID priorities
  – Announce in early 2004
  – Application receipt date 6/1/04
  – Funding date late 2004 or early 2005
White House Memorandum (May 1994)

“Each Federal R & D Agency is expected to significantly enhance the utilization of merit review with peer evaluation and competitive selection in Federal R & D Projects. Research not subject to merit review with peer evaluation is expected to decline and funding in these areas should be moved into areas of merit review research with peer evaluations.”
The Changing Research Environment at CDC
CDC Peer Review Policy

• Implemented October 1, 2002
• All CDC research awarded on/after October 1, 2005 will be determined by external peer review
CDC Director, Dr. Gerberding: top priority is to enhance and expand extramural research activities

- Fund grants in high priority public health areas
- Attract experienced extramural researchers to public health
- Develop new external capacity for public health research nationwide
- Align CDC extramural research program more closely with NIH
CDC Director, Dr. Gerberding: top priority is to enhance and expand extramural research activities

- Modify internal systems to provide seamless interface with NIH extramural programs
- CDC processes and procedures same as NIH “One Department”
- CDC will establish Public Health Research function in the Office of Director
- Set research priorities and provide peer review oversight
The Changing World Environment
Bioterrorism Threat Agents

• Little familiarity
• Little or no immunity
• Little research
• Deliberate release of agent of bioterrorism or naturally occurring infectious disease?
Biological Agents of Highest Concern (Category A Agents)

- *Variola major* (Smallpox)
- *Bacillus anthracis* (Anthrax)
- *Yersinia pestis* (Plague)
- *Francisella tularensis* (Tularemia)
- Botulinum toxin (Botulism)
- Filoviruses and Arenaviruses (Viral hemorrhagic fevers)
- Also select Category B Agents
Is That an Epidemic — or a Terrorist Attack?

Bioterrorism Is the Least of Our Worries

By Jonathan B. Tucker

The news media are fascinated with bioterrorism. After a New Yorker article this week quoted unnamed Central Intelligence Agency analysts who speculated, apparently wrongly, that the outbreak of West Nile fever in New York could have been the work of Iraqi terrorists, a number of television news programs reported the story. And earlier this month, ABC's "Nightline" aired a weekend docudrama in which a hypothetical anthrax attack on the subway system of a major city infects more than 50,000 deaths.

This sort of worst-case scenario is extremely unlikely. In truth, most terrorists aren't interested in staging catastrophic biological attacks, and those who are would have significant technical hurdles to overcome. Over the past century, not a single biological weapon has caused the mass destruction presumed by the media.

In the late 1980's in Japan, the Aum Shinrikyo cult, which had vast financial resources, recruited scientists from leading Japanese universities to develop bioweapons. But even though the cult acquired anthrax bacteria and botulinum toxin and carried out several attacks in Japan, no injuries or deaths were reported. The cult then resorted to sarin, a chemical nerve agent. In March 1995, the group released the poison on the Tokyo subway, killing 12 people and injuring more than a thousand.

Without technical help, small terrorist cells would have a hard time mounting a large-scale biological attack. Germs suitable for warfare are difficult to mass-produce and even harder to disseminate effectively. Microbes might be spread, for example, as an aerosol cloud, but it is technically complex and dangerous to produce a concentrated aerosol that could infect thousands of people. Contaminating urban water supplies is also beyond the ability of most terrorists, mainly because a huge volume of harmful agent would be needed to overcome the effects of dilution, chlorination and filtration.

A Lethal Weapon We Must Learn to Recognize

By Jessica Stern

CAMBRIDGE, Mass.

That flurry of rumors last week about the origins of the encephalitis outbreak in the New York metropolitan area proved how anxious we are about biological terrorism.

After an article in The New Yorker quoted unnamed Central Intelligence Agency sources who speculated that the West Nile-like virus might have been spread in an Iraqi biological attack, the C.I.A. found itself having to reassure the public that this chain of events was highly unlikely. And indeed, it is.

For one thing, West Nile encephalitis is a relatively mild disease, and Saddam Hussein has far more virulent agents in his arsenal. For another, the outbreak has all the earmarks of a naturally occurring infectious disease, according to the Centers for Disease Control and Prevention.

But this case illustrates one of the most troubling aspects of biological terrorism: it can be extremely difficult to distinguish germ warfare from a natural outbreak of disease. After all, this is not the first time that biological attacks have been blamed for sudden epidemics. In 1997, when foot-and-mouth disease struck pigs in Taiwan for the first time in 30 years, the Taiwanese government was forced to slaughter some four million hogs. Taiwanese farmers, without any evidence, suspected that China had deliberately introduced the disease on the island to damage the economy.

After Cuba suffered an epidemic of dengue fever in 1981, it accused the United States of biological aggression. In 1997 Cuba made a similar claim, charging that the United States had dropped crop-eating pests from a low-flying plane.

On the rare occasions when biological weapons have been used or accidentally released, scientists and government officials often first assumed that the epidemics were natural outbreaks.

Our uncertainty about a virus's origin is a warning.

For instance, many American security experts initially believed that a 1979 outbreak of anthrax in the Soviet Union was caused by contam-
Lessons Learned:
Emerging Infections/Bioterrorism Outbreaks

• Importance of
  • surveillance
  • prompt epidemiologic investigation
  • laboratory capacity
• Disruption of travel and commerce
• Global implications of local problems
• Critical linkages and partnerships
• Communications
NCID Responds to the Changing CDC and World Environments
Centers for Disease Control and Prevention

- An Agency within the Department of Health and Human Services
- Long tradition of surveillance, epidemiology, and building state, local, and public health capacity
- About 11 Centers, Institute, and Offices
- Including the National Center for Infectious Diseases (NCID)
NCID/CDC Extramural Research:

- In August 2002, NCID Director Dr. Jim Hughes established Office of Extramural
- Administer Biodefense and Emerging Infectious Disease Research
- Oversee peer review of NCID research
- Separate intramural scientists from extramural research program
In January 2003, OER announced the availability of up to $8 M for research in Biodefense and Emerging Infectious Diseases in FY 03 and FY04.

Invited applicants to submit applications for investigator-directed research with application Receipt Date February 1 and June 1 by responding to the National Institutes of Health (NIH) NOT-AI-02-023 which was released on May 17, 2002, by the National Institute of Allergy and Infections Diseases at (http://grants1.nih.gov/grants/guide/notice-files/NOT-AI-02-023.html).
Extramural Research

Supporting extramural research is an important part of NCID's mission. The NCID Office of Extramural Research handles this function.

The subsections below list current research funding opportunities.

**Research funding opportunities**

<table>
<thead>
<tr>
<th>Announcement Date</th>
<th>Description</th>
<th>Date of Receipt Deadline</th>
</tr>
</thead>
</table>
| Jan 3, 2003       | BIODEFENSE AND EMERGING INFECTIOUS DISEASES RESEARCH - CDC NCID will fund $8 M in FY03 through collaboration announcement with NIH NIAID  
* See [NCID biodefense collaboration with NIH NIAID](#)  
* See original NIH Notice NOT-AI-02-023, May 17, 2002 | Cycle I: Feb 1, 2003  
Cycle II: June 1, 2003 |
NCID/CDC Extramural Research Announcement

• Grant applications are received at NIH Center for Scientific Review (CSR)
• Received, referred to Initial Review Groups, and reviewed by NIH Study Sections or special emphasis panels
• Applications that align with CDC priorities are assigned to NCID/CDC
• Most highly meritorious applications receive secondary review at CDC
• Selected applications are funded and administered by NCID/CDC
NCID/CDC Biodefense and EID Research Priorities

• Further the understanding of surveillance, prevention, and control of potential bioterrorism agents, with an emphasis on the Category A and selected Category B agents, through:
  – Enhanced detection systems
  – Innovative surveillance systems
  – Environmental sampling and pathogen detection systems (including air, food, water or surface) and disinfection strategies
  – Residual indicators of human immunity (e.g., evaluate human immune correlates of protection)
  – Enhanced linkages between human and veterinary medicine
NCID/CDC Biodefense and EID Research Priorities

- Innovative approaches to prophylaxis and treatment (e.g., for botulism)
- Assessment of aerosol risk for humans
- Assessment of the efficacy of vaccinia immune globulin for smallpox complications
- Identification of risk factors for adverse reaction to the smallpox vaccine (including genetic or immune)
- Enhanced linkages (for surveillance, prevention, control, communication, and education) between academic centers, healthcare facilities, and local and state health department
NCID/CDC Biodefense and EID Research Awards FY03

- Nine R01 grants awarded for about $8.6 M
  - Human and animal syndromic surveillance
  - Treatment of Category A bacteria
  - Immune response vaccinia anad B anthracis
  - Detection methods for Category A pathogens

- Training Grants
  - Train scientists from developing countries to engage in infectious disease research
  - Co-funded 5 applicants with the NIH Fogarty International Center
Funding Opportunities

• Announced in collaboration with NIH NIAID
  – Award FY03 $9 M
  – Award FY04 $9 M (application receipt date 6/1/03)
• Separate NCID CDC announcement complimentary to NIH NIAID priorities
  – Announce in early 2004
  – Application receipt date 6/1/04
  – Funding date late 2004 or early 2005
NCID/CDC Extramural Research: changes in how we do business

- Publish announcements in the NIH Guide, in addition to CDC site
- Format Announcements in NIH template familiar to most researchers
- Applications for Biodefense funds are received and reviewed by NIH Center for Scientific Review
- Funding mechanism is R01
- Standard Application Receipt Dates (February, June, October)
NCID/CDC Biodefense and EID Research Awards FY05

• RFA or Program Announcement in NIH Guide for Grants around February 2004
• Application receipt date probably June 1, 2004
• Scientific merit review October and November 2004
• Secondary Review and award early 2005
NCID/CDC Biodefense and EID Research Awards FY05

• Research priorities similar to those in FY03 and FY04 Announcements
• Also consider HHS strategic plan for biodefense research: the Regional Centers of Excellence
• NIAID funded 8 RCEs to prepare for bioterrorism attack or other public health crises
Watch NIH news for more information of these recently funded Centers.

CDC biodefense and EID research priorities likely to be addressed *in part* through investigator-directed research fostered the facilities and scientific support of the RCEs.
Conclusions

- Public-private partnerships established through investigator-directed, peer reviewed, extramural research will greatly enhance our capacity to detect, prevent, and control emerging infectious diseases and prepare for potential future bioterrorism events.
- Please join us in this partnership by applying for grant support for FY05 by responding to the Announcement in FY04.
- Watch the CDC/NCID OER website and the NIH Guide and contact me at mlerchen@cdc.gov with further inquiries.
Thank You!