Biosecurity: Enhancing Security in an Increasingly Unsecure World

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Biosecurity and Global Health: Understanding the Implications of Major Economic Disparities and Environmental Dislocations
Seeking Security in an Unsecure World: The Military and National Security Calculus

Expanding Conflict Zones, Political Instabilities and Terrorism

- WMD Proliferation
- New Power Centers
- US Retrenchment: Geopolitical/Fiscal
Biosecurity

- collective term embracing biodefense, public health and dual-use technologies
- fundamental component in national security
- understanding how changes in biological systems threaten health and societal stability
  - directly and indirectly
  - infectious disease, food production, climate change
  - disruption of transportation and supply chains, economic loss and risk of civil disorder
- chronic social and economic instabilities as triggers of political turmoil and military conflict
Biosecurity

**biodefense**

- combating malevolent biological assault from terrorists/nation states
- not just humans as targets (animals, food supply)
- not just bugs (dual-use biology and disruption of key body biological pathways)

**public health**

- combating naturally occurring biological threats

**dual-use technologies**

- scientific methods and knowledge which can be used for both beneficent and malevolent purposes
Infectious Disease: A Powerful Force in Human Evolution
OUTBREAK: Deadliest Pandemics in History

What is a Pandemic?
Derived from the Greek word pandémion meaning “pertaining to all people,” a pandemic is a widespread disease that affects humans over a wide geographic area.

Key:
- PANDEMIC
- DEATH TOLL

Outbreak: Deadliest Pandemics in History

MEASLES
7th Century BC - 1963
200 million

HIV/AIDS
1981 - TODAY
25+ million

PLAGUE OF JUSTINIAN
541 - 560
25 million

SMALLPOX
10,000 BC - 1979
300+ million

SPANISH FLU
1918 - 1919
50 - 100 million

BLACK DEATH
1340 - 1371
75 million

TYPHUS
450 BC - TODAY
4 million

CHOLERA
1857 - TODAY
3 million

HONG KONG FLU
1968 - 1969
1 million

THIRD PANDEMIC
1855
12 million

Although the following viruses do not have a figure for total amount of lives claimed, they continue to terrorize various areas around the world.

HONORABLE MENTIONS

MALARIA 1800 - Today
Common Symptoms
Chills, Headache, Fever, Jaundice, Muscle Pain, Nausea, Vomiting, Seizures

Death Toll
According to the World Health Organization's 2020 World Malaria Report, an estimated 780,000 people are killed by the virus every year.

TUBERCULOSIS
700 BC - Today
Common Symptoms
Chest Pain, Cough, Fever, Chills, Fatigue

Death Toll
There are almost 2 million tuberculosis-related deaths worldwide every year.

YELLOW FEVER
16th Century - Today
Common Symptoms
Bleeding, Fever, Nausea, Vomiting, Delirium, Sequins, Jaundice

Death Toll
Worldwide, 30,000 deaths are caused by the infection every year.

Ring Around the Rosie,
a Pocket Full of Plague
Legend says the Black Death plaque inspired the children’s rhyme “Ring Around the Rosie,” which alluded to the rash-like rings and spots of the deceased victims.

Sources: Mayo Clinic // Centers for Disease Control and Prevention // World Health Organization // New York Times // National Center for Biotechnology Information

A collaboration between Good and Column Five
“I will show you fear in a handful of dust”
T.S. Elliot
THE SOVIET BIOLOGICAL WEAPONS PROGRAM
A HISTORY

MILTON LEITENBERG
RAYMOND A. ZILINSKAS
Biosecurity

Today

- bioterrorism: low probability, high consequence
- natural infections: high probability, high consequence

2020 and beyond

- bioterrorism  
  - an expanded risk beyond bugs
- outpacing natural infectious diseases  
  - old foes, resurgent foes and new EIDs
- synthetic biology  
  - the ultimate dual-use technology
Preparedness:
Building Resilient Systems and the “All Hazards” Challenge

- How do you stay one step ahead of the nation’s threats when they’re always moving in new directions?
Preparedness: Building Resilient Systems and The “All Hazards” Challenge
“For most of us design is invisible until it fails”
Bruce Mau
Building Resilient and Agile Systems for Biosecurity

- Infectious Diseases of Natural Origin
- Environmental and Ecological Impacts on Disease Emergence
- Bioterrorism
Infectious Diseases: A Shared Global Risk

#1
- cause of neonatal and maternal death worldwide
- economic impact of disease via premature death, disability and reduced productivity
- growing drug-resistance as most important clinical threat in both industrialized nations and DCs

#2
- cause of death worldwide

#3
- cause of death in US and Europe

The Imperative for new R&D Strategies and Investments in Diagnostics, Drugs and Vaccines
Tuberculosis

- 2.2 billion people infected
- every 20 seconds a person dies from TB (1.77 million/year)
- second leading infectious cause of adult death
- #1 infectious killer for individuals with HIV/AIDS
- kills more women than all other maternal mortality causes combined
- emergence of multi-(MDR) and extreme-(XDR) resistant strains

No New TB Drug for 40 Years
Outpacing Infectious Diseases

- new patterns of exposure and disease spread
- emerging infectious diseases (EIDs)
- growing resistance to existing Rx and vaccines
Global Transport and Trade: New Interactions of People, Animals and Product Supply Chains

The Super Vector

World Container Traffic Doubled Since 1997

Billion Cross-Border Travelers

Global Food Networks
1407 species of human pathogens

- 538 bacteria
- 57 protozoa
- 208 viruses
- 317 fungi
- 60% are zoonoses
- over 70% zoonoses arise from interactions with wildlife
- Emerging Infectious Diseases (EIDs)
  - 58 in last 25 years
  - viruses significantly over-represented
  - helminths under-represented
The Global Public Health Challenge Posed by Rapid Urbanization in Developing Countries

- High Disease Transmission
- Lack of Safe Water
- Bush Meat Food Chain
- Major Deficits in Health Infrastructure
- Expanded Eco-niches and Increased Zoonotic Risks
Emerging Infectious Diseases (EIDs)
The Ever Shifting Dimension of EIDs

- West Nile Virus, New York 2001
- West Nile Virus, Dallas, TX 2012
- Monkeypox, USA May-June 2003
- African Swine Fever, Russia 2012
Human Coronaviruses

Emergence of SARS-CoV (PRC 2003)

Emergence of MERS-CoV (KSA 2012)
Maintaining Global Preparedness for a High Virulence Pandemic

- **H1N1**: high transmissibility - low virulence/mortality
- **H5N1**: low transmissibility – high virulence/mortality
- **H5N1 x (H1N1) or (X)**: potential for devastating pandemic
The Rationale for Integration of Historically Separate Domains and Responsibilities

- Most effective control route for zoonotic threats to humans is via the relevant animal population(s).
- Knowledge of the potential impact(s) of ecosystem perturbations on emergence of novel zoonoses must be accorded high priority.
- Disparity in animal and human public health capacity undermines global disease control.
- Food chain safety.

“One Health”

- Human Health
- Ecosystem Health
- Animal Health
Surveillance Systems for the Rapid Detection and Control of Infectious and Parasitic Diseases

- **Profile**: Signatures of Pathogenic Organisms
- **Sense**: Global Network of Surveillance and Diagnostic Testing Systems
- **Act**: Rapid Analysis and Response to Diagnostic and Surveillance Information
Geodemographic Information Systems (GIS): Real-Time, Front Line, Ground Zero Data from Field Sampling and Sentinels
## Geodemographic Information Systems: Mapping Disease Patterns and Modeling Trends

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<th>Anomaly Detection and Early Alert</th>
<th>Disease Progression</th>
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### Satellite Surveillance and Predictive Modeling of Disease Trends
Biometrics and Infectious Disease Surveillance in a World of Rapid Global Transit
● 398 WHO-verified outbreaks 1996-2009

● median times
  – 23 days for event detection
  – 32 days for public communication
  – 35 days for official laboratory confirmation
  – 48 days for inclusion in WHO Disease Outbreak News
“Insufficient data, Captain”

“Insufficient data is not sufficient, Mr. Spock. You’re the Science Officer. You’re supposed to have sufficient data all the time”

Star Trek
The Immunity Syndrome
Sensor Networks for Remote Health Status Monitoring: Wireless Integrated Data Systems

- geolocation data (where)
- temporal information (when)
- contextual information (what)
- improved decision support (action)
Detection of Infectious Disease Threats:

Not A Hazmat or Wide Area Sensor Network Solution

Emergency Rooms and Farms Will be the Front Line
The Single Most Important Leverage Point For Rapid Mobilization of Resilient Responses to Epi-/Pandemics, Epizootics and WMD Bioterrorism

Earlier Diagnosis and Intervention Saves Lives

Improved speed, breadth and accuracy of clinical diagnosis

- faster Rx
- accurate Rx
- prophylactic Rx for incident personnel
- robust triage
  - rationing
  - reassurance of “worried well”
  - quarantine decisions
- real time disease surveillance data
- faster ID of incident evolution
- faster incident containment and exposure controls

The Single Most Important Leverage Point For Rapid Mobilization of Resilient Responses to Epi-/Pandemics, Epizootics and WMD Bioterrorism
Genome Sequencing, Microbial Identification and Epidemiology

E. Coli Strain STEC 0104: H4 (Germany 2011)
Biosecurity

- Identification of the threat spectrum (awareness, intelligence)
  - static, dynamic, overt or covert
  - natural or anthropogenic
- Adequacy of detection, pre-emption, preparedness, recovery and attribution capabilities (resiliency)
- Risk assessment and needed level of investment in protection and preparedness (public policy)
Biosecurity

- who pays for preparedness? (public policy, market dynamics)
- who is responsible/accountable for biosecurity? (public policy, organization, politics, media responses)
- myriad ethical and legal issues (surveillance, civil liberties, rationing, counter-terrorism targets, publication of dual-use knowledge)
Preparedness: Building Resilient Systems

- Are the necessary resources available: financial, personnel, skills, infrastructure?
- Have all elements been tested under simulated emergency situations?
- Are organizational structures and processes sufficiently agile for rapid response?
- Are roles, responsibilities and accountabilities defined and understood for every constituency involved?
  - From local to global
The ‘Fog of Disaster’: Crisis Standards of Care and Proliferation of Unanticipated Events and Consequences
Overload and Triage

Education and Training

Diagnostic Accuracy

Infection Control

Availability of Therapy

Overload and Triage
The Three Core Components of Bioincident Management

Command and Decision Authorities

Healthcare System and Public Health Capabilities

Maintenance of Civil Order and Public Trust

- robust inter-operable communication networks for real-time situational awareness and rapid actions
- managing the media and the ‘worried well’
- transparency, credibility and public trust
Key Success Factors

- tested disaster management plan
- responder training and education
- command structure
  - demarcated roles, responsibilities, authority
  - robust communication channels
- single source POC for key interfaces
  - ground zero staff (multiple ground zeros in CBW)
  - emergency services and first responders
  - medical/public health
  - politicians and inter-agency coordination
  - conventional media and social media
Building Resilience: Complex Systems-Based Integration of Diverse Functions and Organization
National Biomonitoring Notification Architecture

CIVILIAN

Biowatch

DEPARTMENT OF DEFENSE (DoD)

Installation Protection

Coordinated Data: Positive Detections

Interagency National Operations Center

Networked Information: Verified Notifications
The Lag Phase in Bioincident Detection

Primary Care Physicians and Pharmacists

initial non-specific illness

progressive illness

unusual illness patterns

Hospitals

BIOINCIDENT CONFIRMATION
Consequence and Crisis Control in a Bioincident

COMMAND CENTER

- public health
- logistics
- communications
- medical
- law
- coordination
- local
- national
- international
- regional

Primary Care Physicians and Pharmacists

“The Worried Well”

Hospitals

- acute care
- triage
- mortuary

Neighborhood Emergency Help Centers

- patient registration
- Dx triage
- transport logistics
- mass Rx/vaccination

Media

Community Outreach and Citizen Mobilization

- police, EMS
- volunteers
- military
Cyber-Attacks and Vulnerable Infrastructure: Compromising Critical Systems
Use of GIS for Management of Population Movement, Healthcare Facilities and Supply Chains for Optimum Bioincident Control
Distribution of Medical Emergency Supplies for a Major Epidemic/Pandemic

- pre-positioning for known threats: The Strategic National Stockpile
- rapid movement by commercial carriers
- managing political/public/media responses for bioincidents with limited or no Rx/vaccine options
Vulnerability of Global, National and Local Supply Chains in a Major Epidemic/Pandemic

- “just-in-time” supply networks
  - major hospitals 2/3 deliveries per day
- out-patient prescription drugs
  - insurance company limits on prescription volume (USA)
- majority of drug intermediates, excipients and final products sourced off-shore
- 95% generic drugs used in US (64% of total Rx) are made off-shore, primarily in PRC and India
- no national stockpile for routine prescriptions
Medical Countermeasures (MCMs) for Special Populations: Emergency Use Authorization

- Children
- Pregnant
- Aged?

- Immunosuppressed
- Impaired Major Organ Function
- ICU-Critical Care
Legal Aspects of Public Health and Counter-Terrorism Actions to Contain Bioincidents

- suspension of civil liberties
- imposition of quarantine
- triage decisions and rationing
- mandatory medical examination and treatment
- mandatory treatment with unapproved drugs and vaccines
  - informed consent
  - indemnification
  - special populations
The Crucial Role of the Media in Incident Management

- Pre-recorded Modules
- Familiar (Trusted?) Face(s)
- Credibility and Reality
- Setting Examples to Limit Civil Disorder
- Authoritative Leadership
- Community Cooperation
Informing the Public: A Critical and Unenviable Challenge

- media sensationalism and public panic
- pressure on governments to make illogical but politically expedient decisions
- in a severe outbreak the shock factor from level of fatalities will be unprecedented in modern peace times with unpredictable consequences
- unpredictable unilateral decisions by other governments, restricting trade, travel and shipment of goods
- extended supply chains might break down completely
Control of Population Movement and Supply Chain Networks
Vulnerability of Global, National and Local Supply Chains in a Major Epidemic/Pandemic

Energy

Net Power Generation in the US by Fuel Source, 2007

- Coal, 48.70%
- Natural Gas, 21.50%
- Nuclear, 19.40%
- Hydroelectric, 6%
- Other Renewables, 2.50%
- Petroleum, 1.60%
- Other Gas, 0.40%
- Other, 0.30%

Energy maps and diagrams showing the distribution of power generation sources across the United States.
Protecting US Infrastructure

- 87,000 communities
- 1800 federal reservoirs
- 80,000 dams
- 2800 power plants (104 nuclear)
- 5000 airports
- 120,000 miles of roads
- 590,000 bridges
- 2 million miles of pipeline
- 85% of infrastructure is privately held
Who Pays for Preparedness?

The Obligate Role of Private-Public Partnerships in Biosecurity Policy
..... and then a technical miracle cure occurs with dramatic rapidity
..... and always created by an individual scientific genius
Drug Discovery and Development: One of the Most Complex Intellectual and Logistical Exercises Undertaken by Industry

- $750 million to $2 billion R&D cost/drug
- 9-15 year R&D cycle
- efficacy
- safety
- cost-effectiveness and outcomes (non-US)
“Fewer countries have discovered, developed and registered drugs to an international standard, than have developed atomic bombs”

Chris Hentshel
Medicines for Malaria Venture
Bad Bugs and Few New Drugs
Comfort and Complacency: The Enemies of Vigilance and Preparedness
Bad Bugs and Few New Drugs

NO ESKAPE!
NO ESKAPE!: Resistant Bugs and Few New Drugs

- increasing resistance in G+ and G- pathogens in hospital and community settings
- the ESKAPE pathogens
  - *Enterococcus faecium*
  - *Staphylococcus aureus*
  - *Klebsiella pneumoniae*
  - *Acinetobacter baumanii*
  - *Pseudomonas aeruginosa*
  - *Enterobacter species*
75% decrease in antibacterials approved from 1983 to 2011

only 16 agents currently in Phase II / III clinical trials

– only 3 as new ‘classes’ with novel mechanisms of action

– absence of new agents for therapy of G^-bacilli

– lack of systemic agents in advanced development for organisms resistant to all current antibacterials
If this virus was killing more of its victims, there’d be lots of questions about whether this vaccine was produced soon enough.

Dr. Michael Osterholm
Director, CIDRAP, Univ. Minnesota
“Millions demand it,
millions refuse it,
and millions don’t know what to think”

John Carroll
Editor, FierceBiotech (23 Oct. 2009)
Vaccine Safety:
Media Sensationalism and Celebrity Quackery
Next-Generation Vaccine Technologies

**pan-vaccines**
- protection against diverse strains of a pathogen
- protection against closely related classes of pathogens

**combating “Agent-X”**
- rapid design and large scale production (weeks versus years) for protection against sudden emergence of an unprecedented pathogen (Agent-X)
Accelerated Manufacture of Vaccines

- convert vaccine production from a ‘biologics’ process to a ‘chemical’ manufacturing process
- reduce R&D cycle from 10-25 years to less than 1 year
- shorten production cycles run-time from 6-12 months to days/weeks
Future Trajectory Trends and Threat Expansion

New ‘Dual-Use’ Technologies
The Expanded Dimension of the ‘Bio’ Challenge

- thinking beyond ‘bio’ as just infectious agents (bugs)

- systems biology
  - targeted disruption of ANY body function
  - novel C and B threats

- synthetic biology
  - exploring biospace: designing new life forms
  - designer organisms to attack materials/infrastructure
ATTGACTGCAA ........................ (design specifications)
Oversight of Synthetic Biology: Risk, Regulation and Responsibility

Biosafety: Risk from Legitimate R&D/Industrialization

Biosecurity: Deliberate Use to Cause Harm

Biohackers and Democratization of New Technology

Screening of Purchases/Supply Transactions

Regulation, Legislation and Codes of Conduct

International Harmonization
Nature (2012) 482, 153

**Comment**

Adaptations of avian flu virus are a cause for concern

Members of the US National Science Advisory Board for Biosecurity explain its recommendations on the communication of experimental work on H5N1 influenza.

Prepared by the American Association for the Advancement of Science in conjunction with the Association of American Universities, Association of Public and Land-grant Universities, and the Federal Bureau of Investigation

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

Report of a Meeting September 13-14, 2012
Dual-Use Research of Concern (DURC)
“Security is always excessive
.....until it’s not enough”
The Fragmented Silos of USG: A Dangerous Vulnerability
Biosecurity: A Classic Complex Systems Challenge

- Global perspectives
- Biological, economic, financial ecosystems

Science and Technology

Public Health and Healthcare Delivery

Intelligence, Foreign Policy and Military Strategies

- Societal priorities and cost of biosecurity
- Political ideologies, intents and capabilities
Biosecurity

one health: humans, animals, ecosystems

urbanization, environmental sustainability and depletion of non-renewable resources

economic and political instabilities and escalating conflict risk

terrorism and international security

International Engagement, Commitment and Political Resolve
naturally occurring infectious diseases pose an equal, if not greater, threat to society as bioterrorism

governments must accord higher priority to ‘biosecurity’ as a integral component of national security and foreign policy

(re)building a national and international infrastructure for the surveillance, diagnosis and containment of infectious diseases is fundamental to future protection against major instabilities triggered by infectious agents, whether of natural or malevolent origins
Addressing Global Challenges in Biosecurity

- mobilize new expertise networks to achieve end-to-end solutions
- funding and assembly of requisite expertise
  - cross-disciplinary, cross-sector
  - obligate role of industrial partners
- sophisticated management of complex collaboration networks whose composition will change constantly with new threats and new technologies
- financial incentives for industry for biodefense products with no civilian markets
- timely and accurate communication to the public and maintaining public support and cooperation
Meeting the Challenge(s) Posed by Global Infectious Diseases

- growing threat awareness as catalyst for action
- availability of powerful new genetic and biotechnology capabilities for discovery of diagnostics (Dx), drugs (Rx) and vaccines (Vax)
- building global surveillance networks using advances in sensor technologies, mobile devices, computing and telecommunications
- strengthening national public health and epidemic/pandemic management capabilities
- new financial incentives for R&D on Dx, Rx and Vax
- global political engagement and commitment
“History is the sum total of the things that could have been avoided.”

Chancellor Konrad Adenauer
“Politics is the art of the possible, the calculated science of survival”

Prince Otto von Bismarck

“Survival owes little to the art of politics, but everything to the calculated application of science”.

Professor Rudolph Virchow (in reply)
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