Biosecurity:
Enhancing Security in an Increasingly Unsecure World

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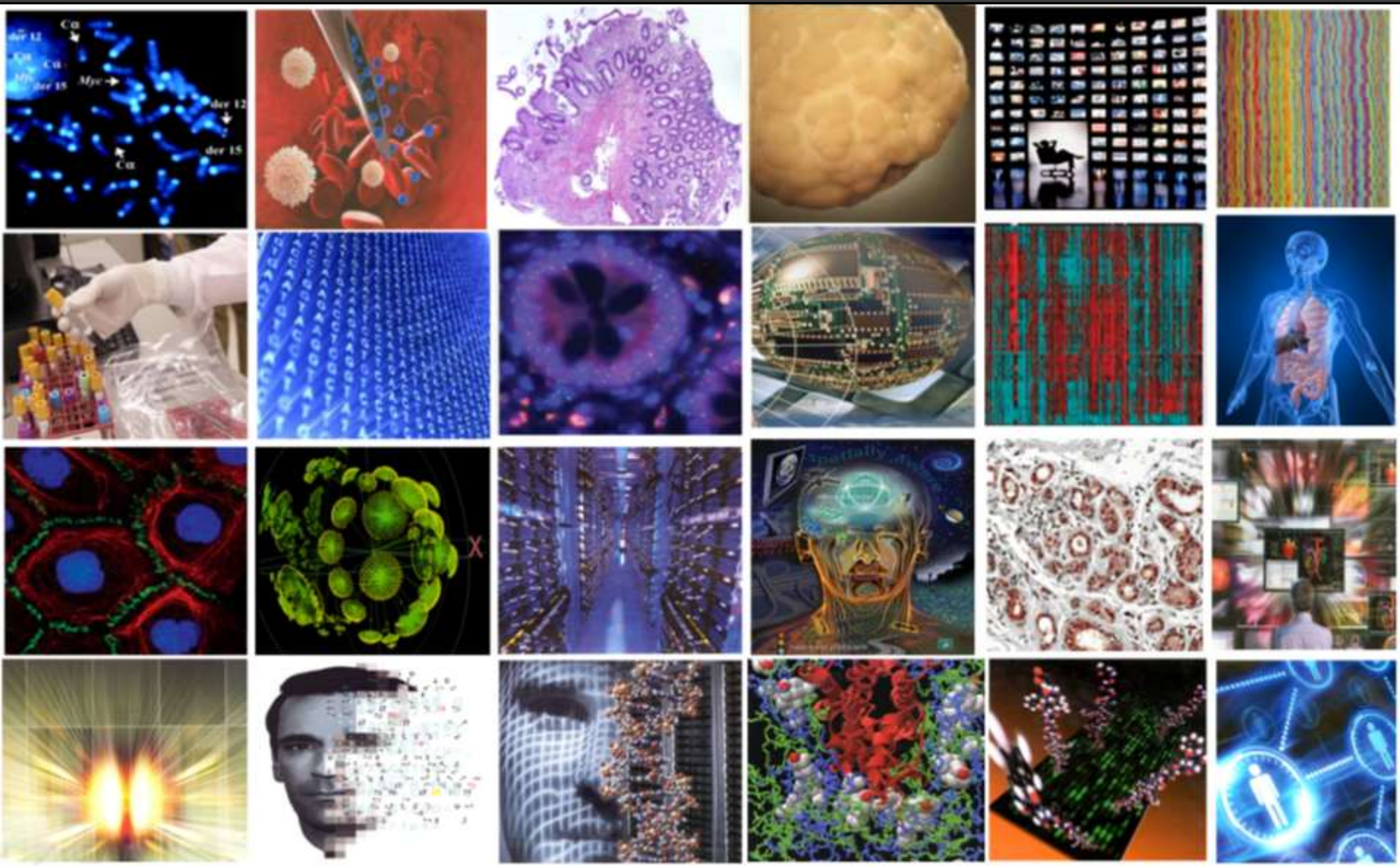
Slides available @ http://casi.asu.edu/



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)

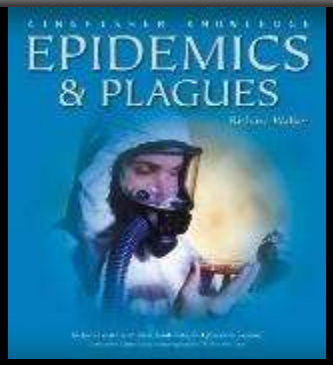
public health

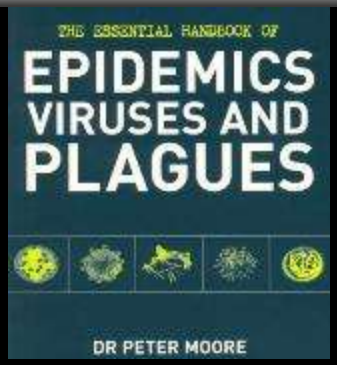
- combating naturally occurring biological threats

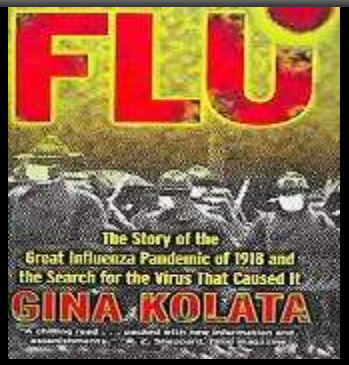
dual-use technologies

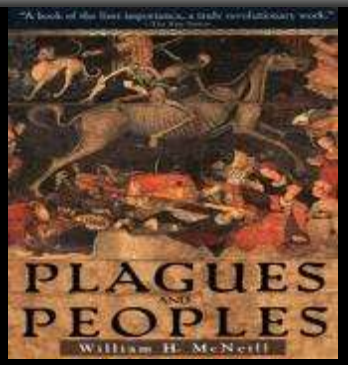
- scientific methods and knowledge which can be used for both beneficent and malevolent purposes

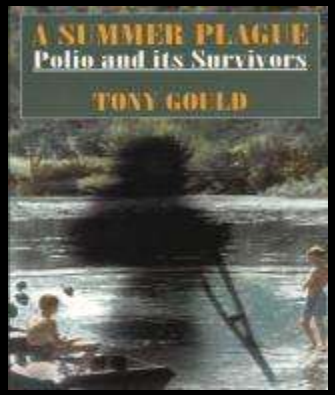
Infectious Disease: A Powerful Force in Human Evolution

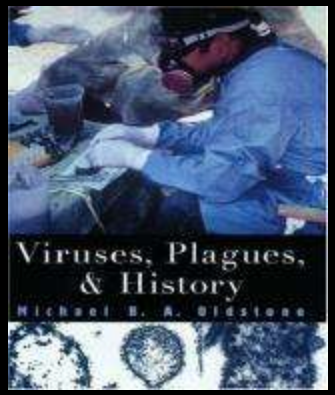


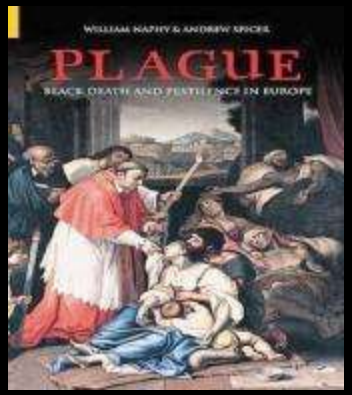


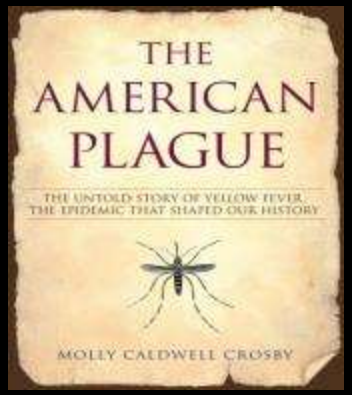


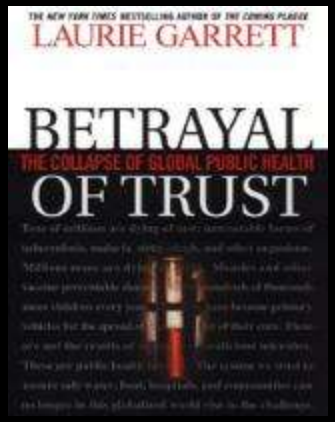


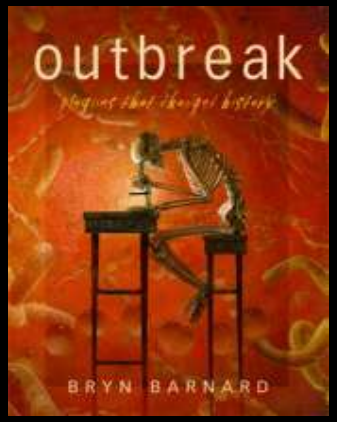


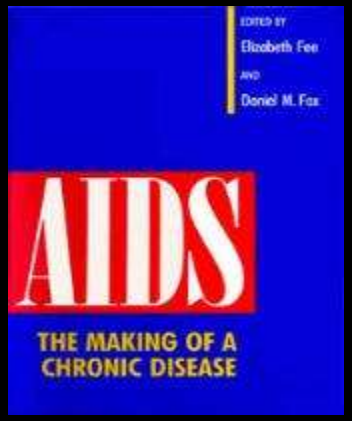


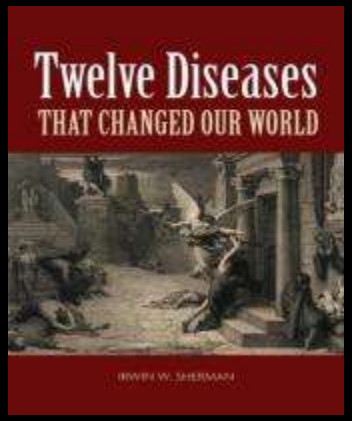




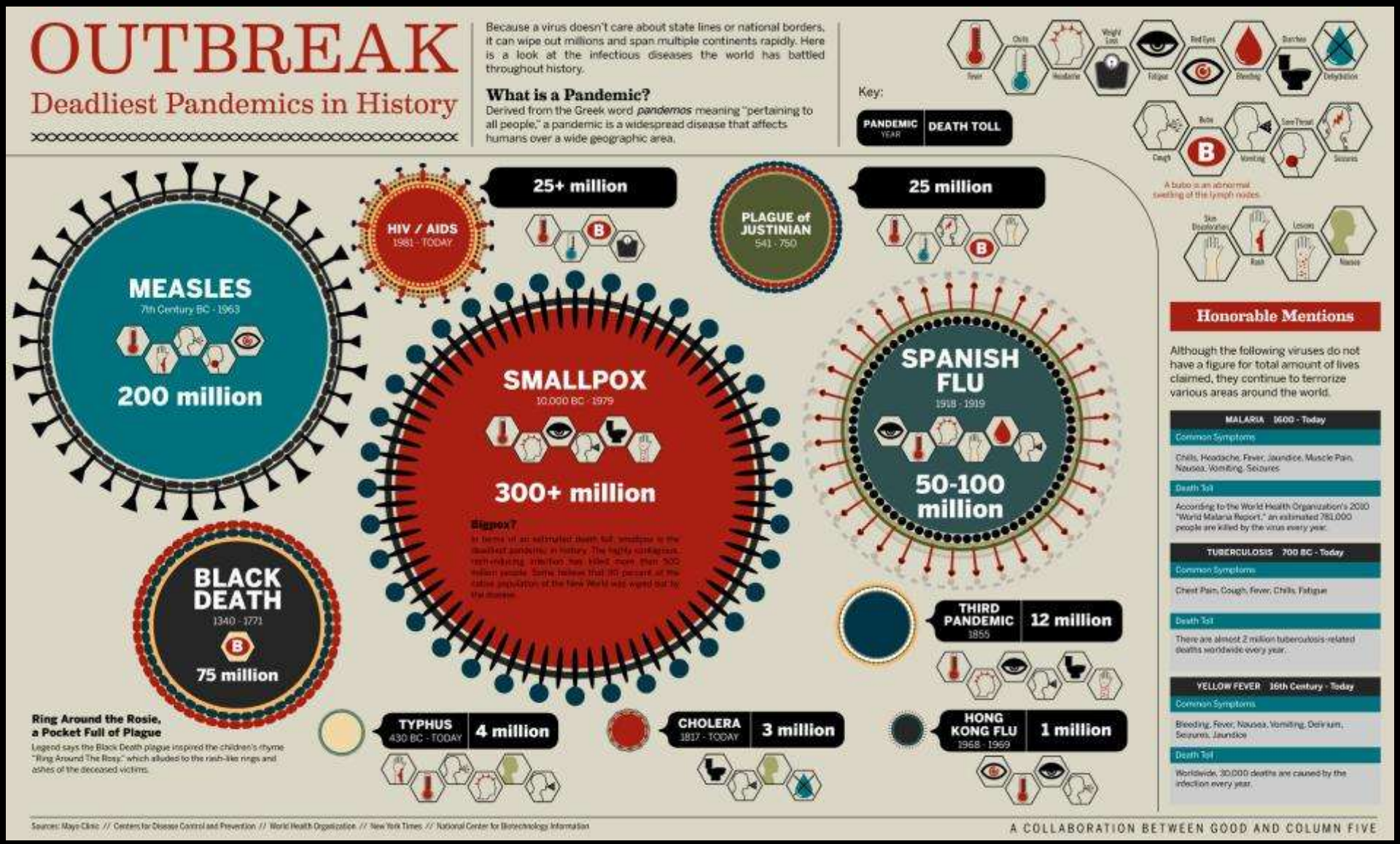


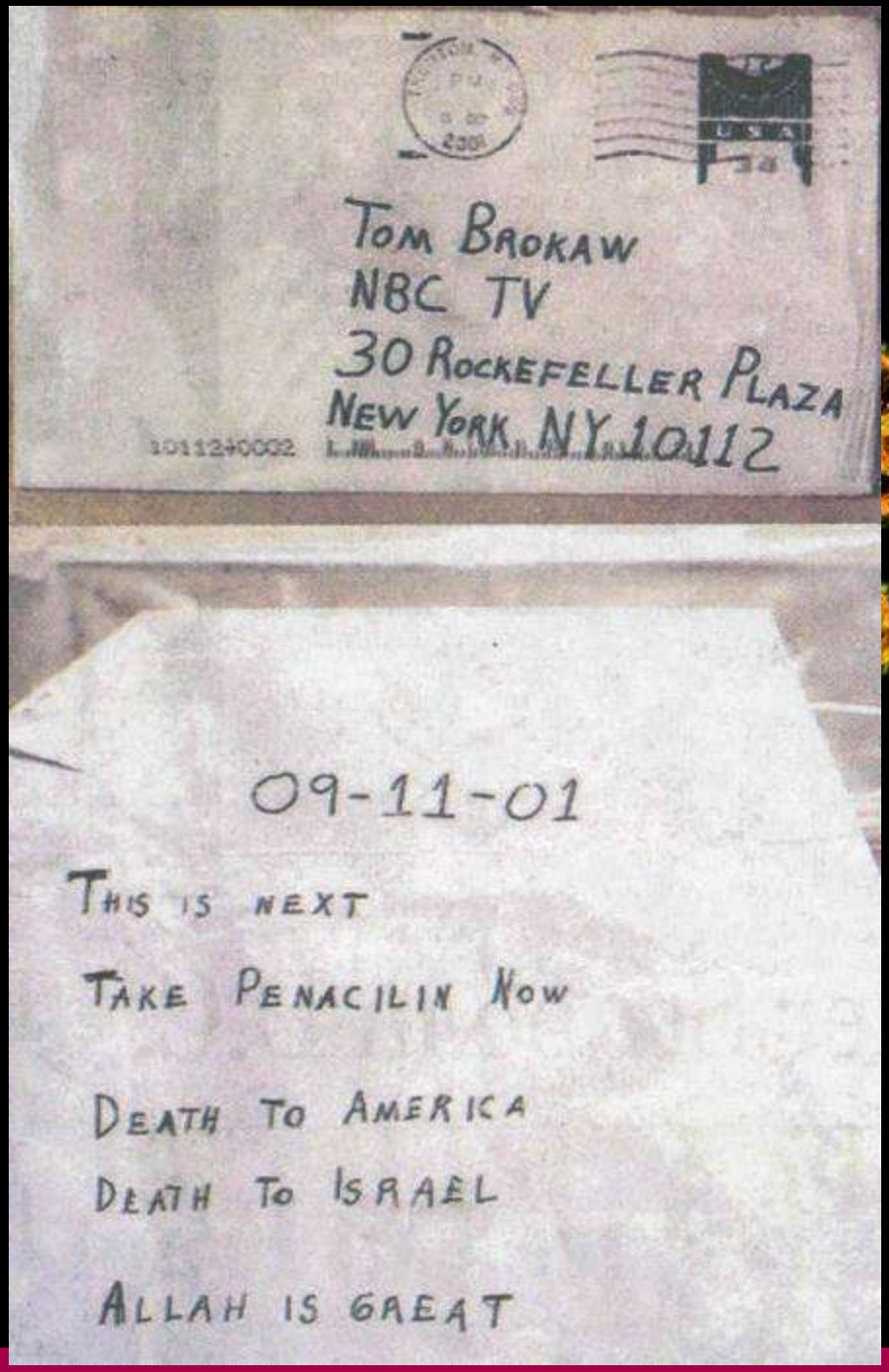






OUTBREAK: Deadliest Pandemics in History





"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

Terrorism and The New Calculus of National Security and Foreign Affairs

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

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

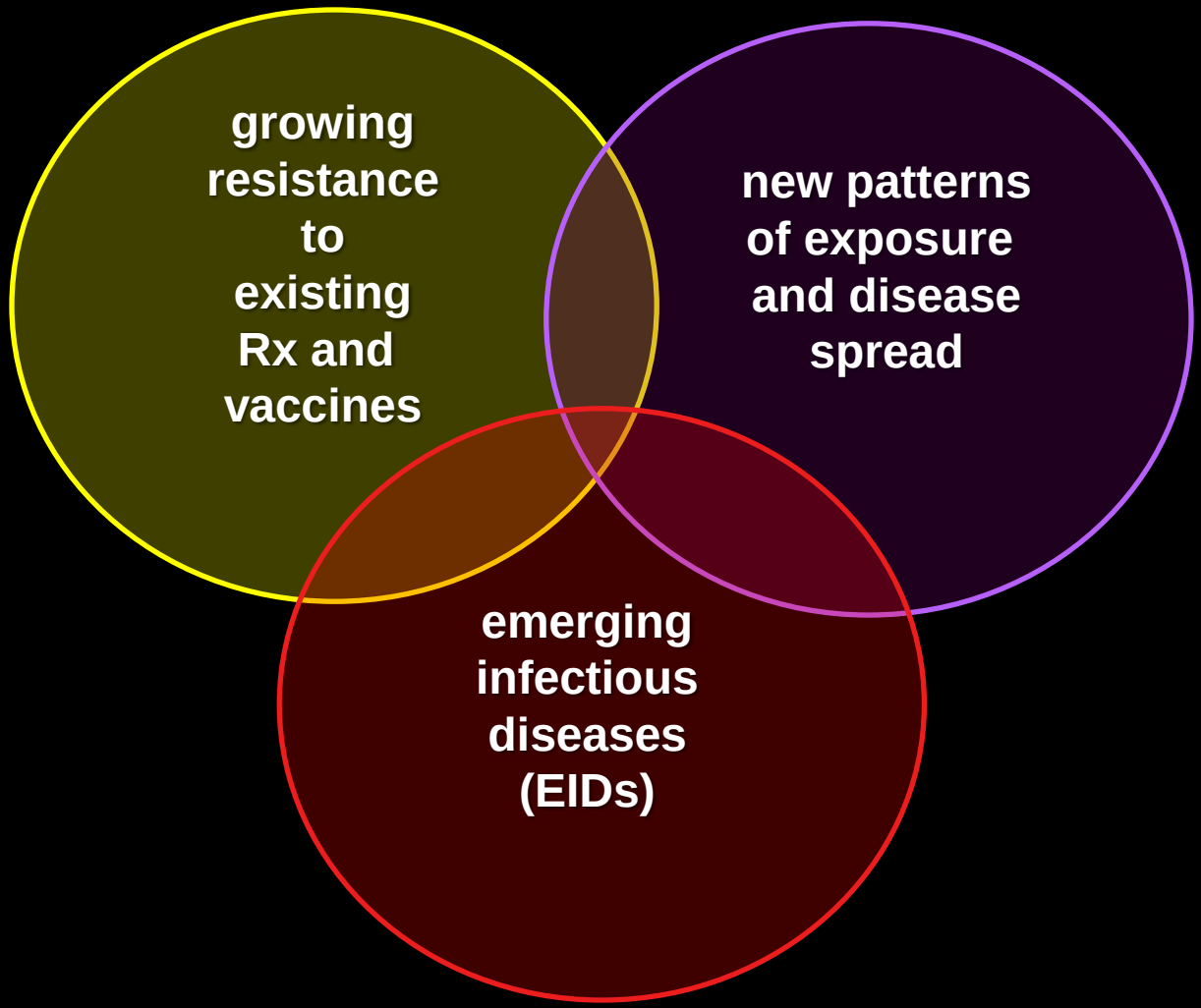
The Imperative for new R&D Strategies and Investments in Diagnostics, Drugs and Vaccines

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

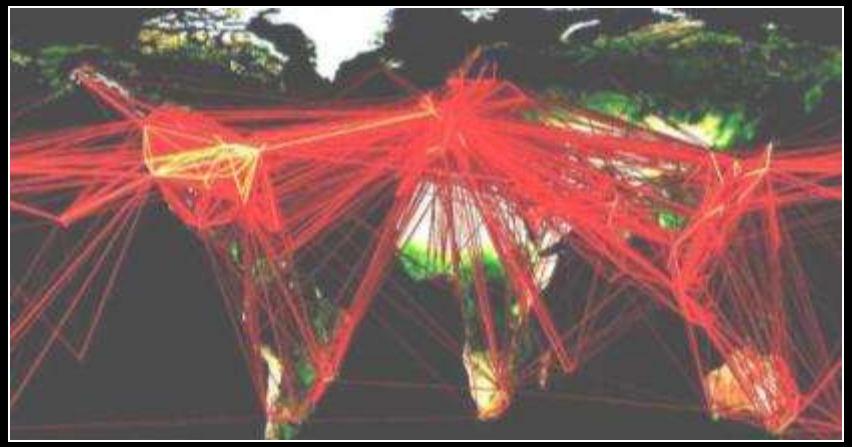
Outpacing Infectious Diseases



Global Transport and Trade: New Interactions of People, Animals and Product Supply Chains

The Super Vector

Billion Cross-Border Travelers



World Container Traffic Doubled Since 1997

Global Food Networks

The Evolving Nature of Human Infectious and Parasitic Diseases

1407 species of human pathogens

- 538 bacteria
- 208 viruses
- 317 fungi
- 57 protozoa
- 287 helminths
- 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

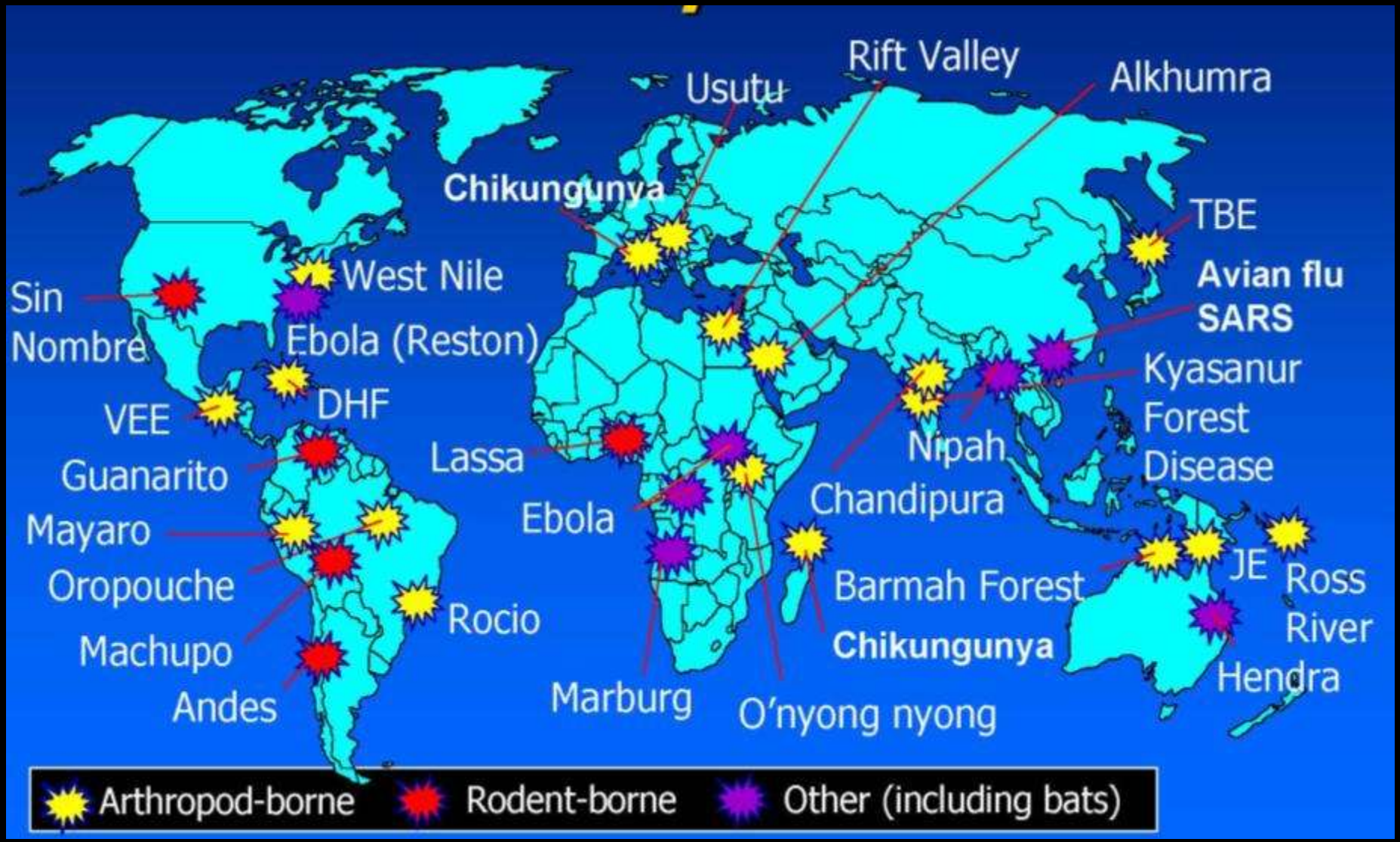
Lack of Safe Water

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

Monkeypox, USA May-June 2003

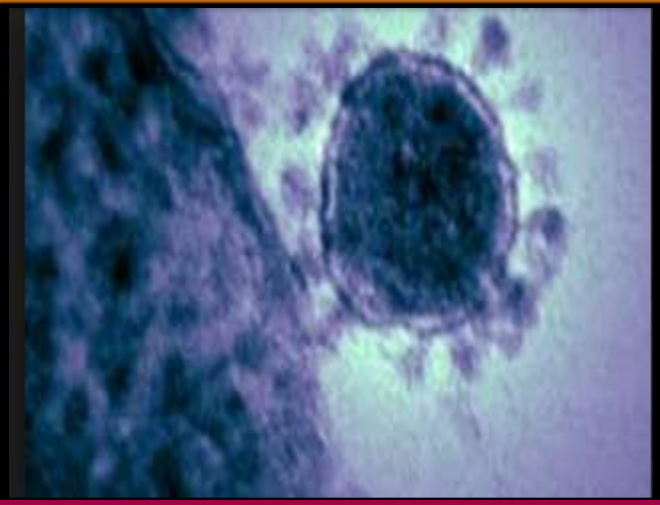
West Nile Virus, Dallas, TX 2012

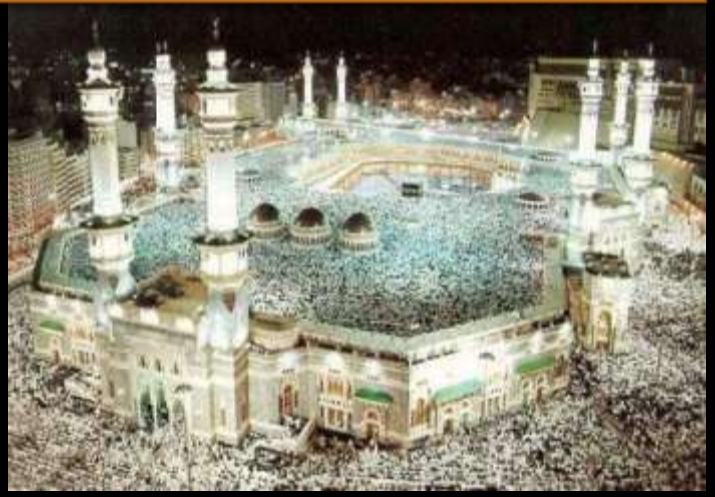
African Swine Fever, Russia 2012

Human Coronaviruses

Emergence of SARS-CoV (PRC 2003)

Emergence of MERS-CoV (KSA 2012)



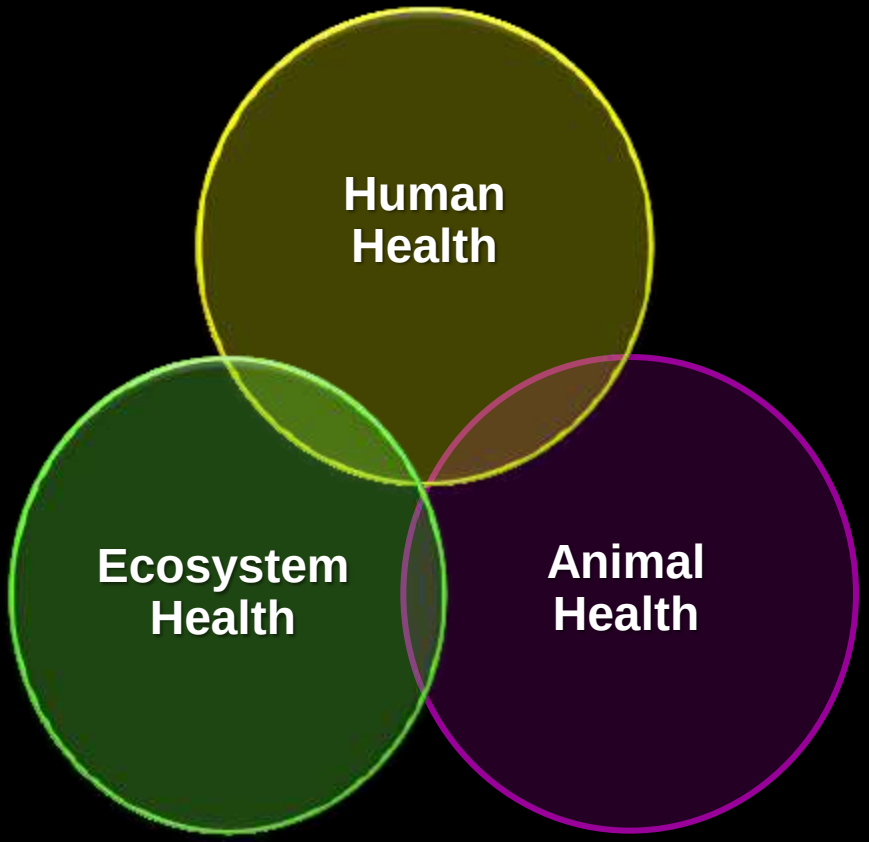


Maintaining Global Preparedness for a High Virulence Pandemic

- H1N1: high transmissibility - low virulence/mortality
- H5N1: low transmissibility – high virulence/mortality
- H5N1 x (H1N1) or (X): potential for devastating pandemic

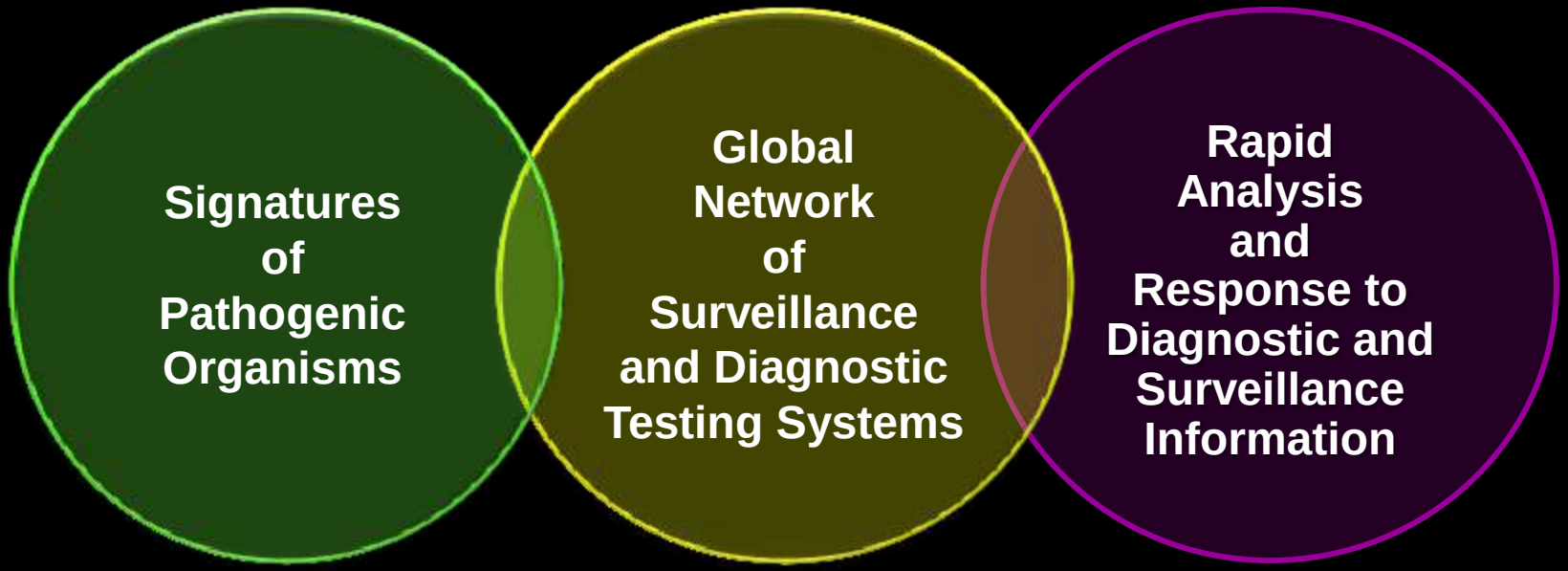
The Rationale for Integration of Historically Separate Domains and Responsibilities

"One Health"



- 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

Surveillance Systems for the Rapid Detection and Control of Infectious and Parasitic Diseases



Profile

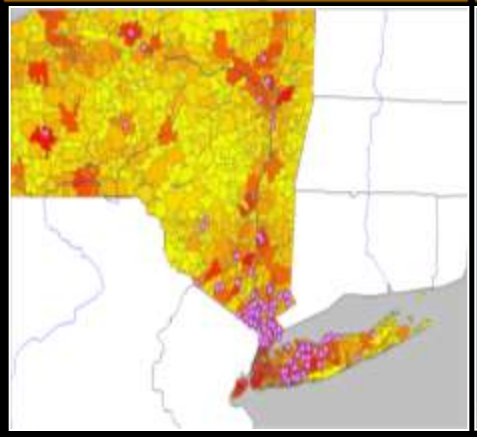
Sense

Act

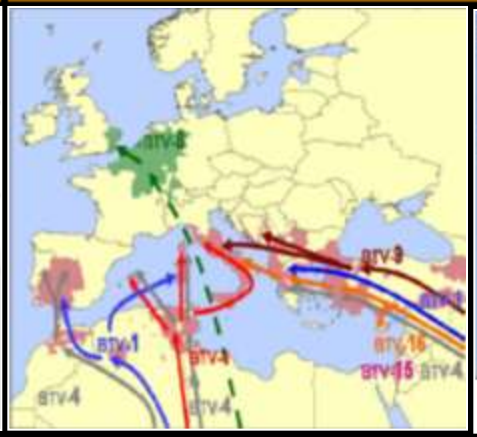
Geodemographic Information Systems (GIS): Real-Time, Front Line, Ground Zero Data from Field Sampling and Sentinels

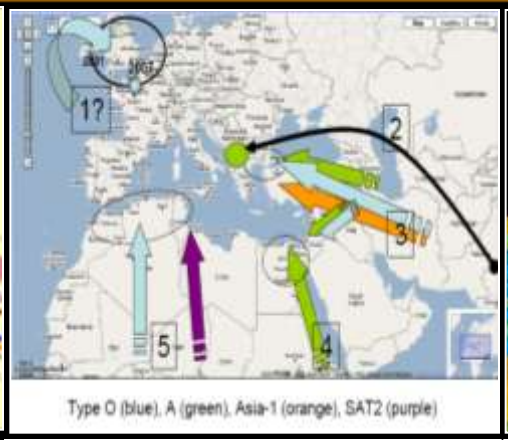
Geodemographic Information Systems: Mapping Disease Patterns and Modeling Trends

Anomaly Detection and Early Alert

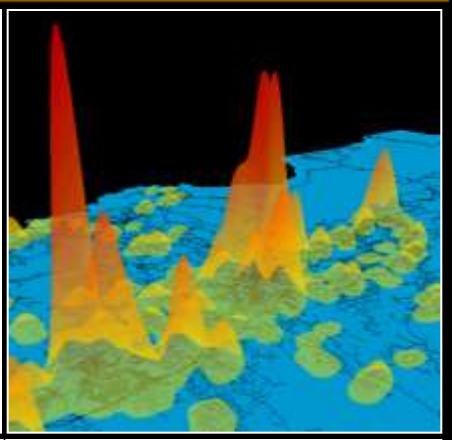


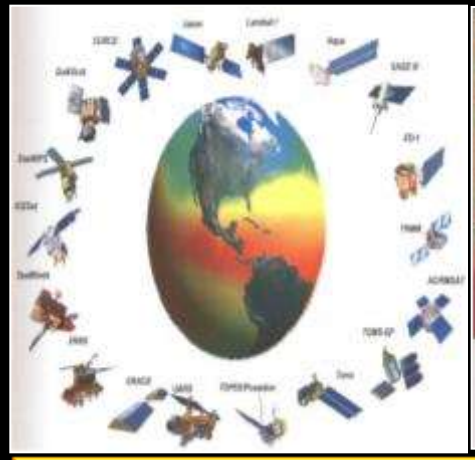
Disease Progression

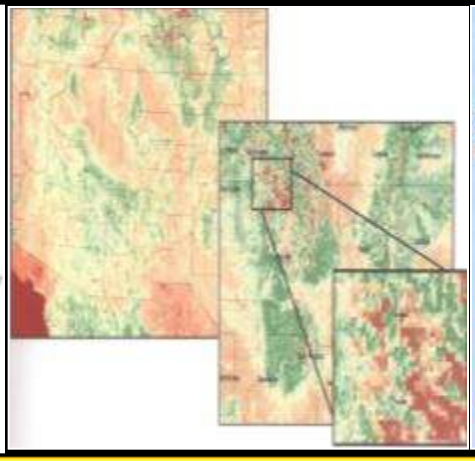


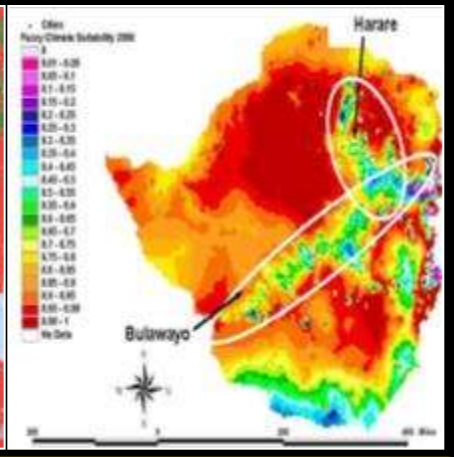


Type O (blue), A (green), Asia-1 (orange), SAT2 (purple)



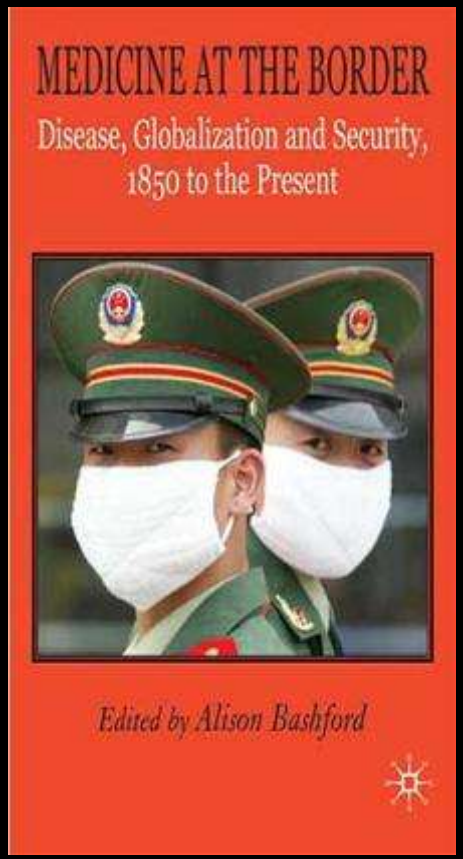


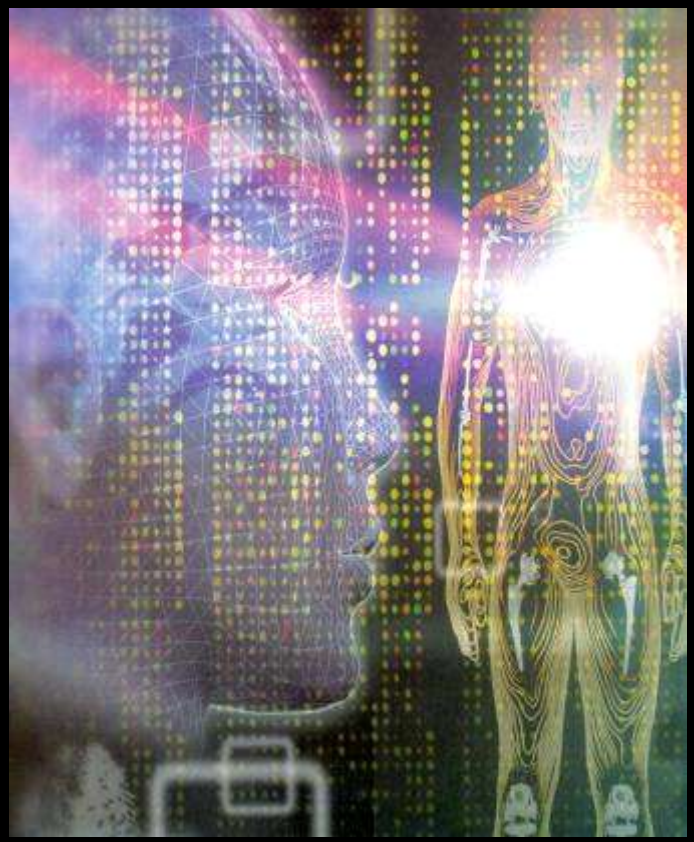




Satellite Surveillance and Predictive Modeling of Disease Trends

Biometrics and Infectious Disease Surveillance in a World of Rapid Global Transit





Global Surveillance Against Infectious Disease Outbreaks
E.H. Chen et. al. (2010) PNAS 107, 21701

- 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

No Ambiguity - No Error: No Problem!
The Omnipresent Dilemma of Uncertainty When Political Leaders Want Certainty

"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

Earlier Diagnosis and Intervention Saves Lives

Improved speed, breadth and accuracy of clinical diagnosis

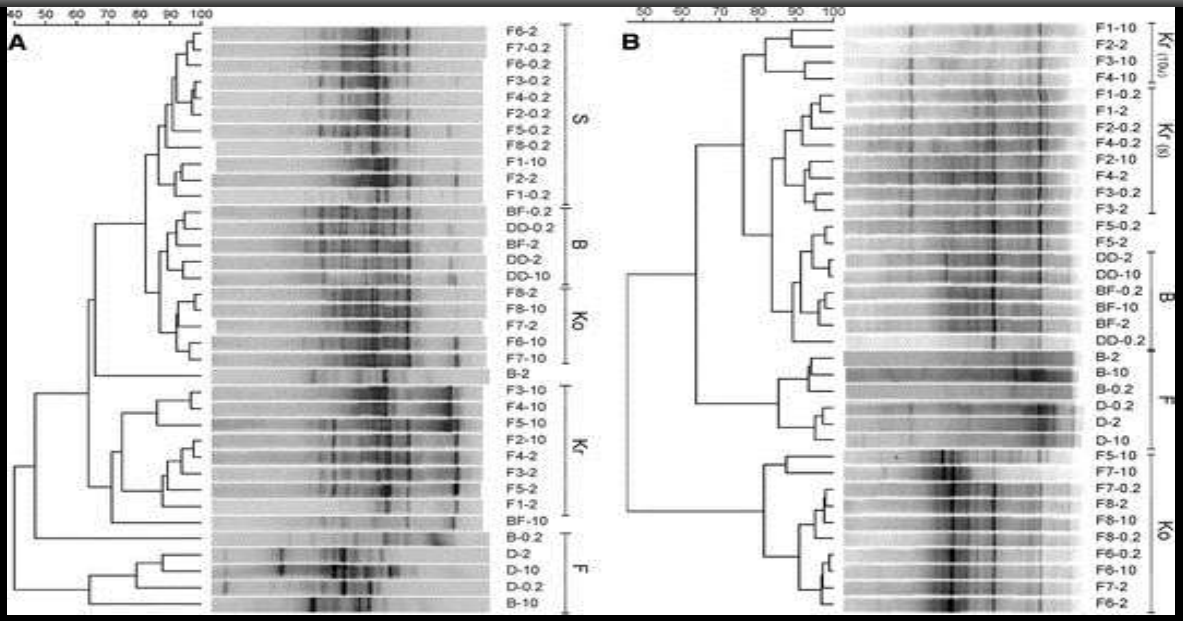
- faster Rx
- accurate Rx
- prophylactic Rx for incident personnel

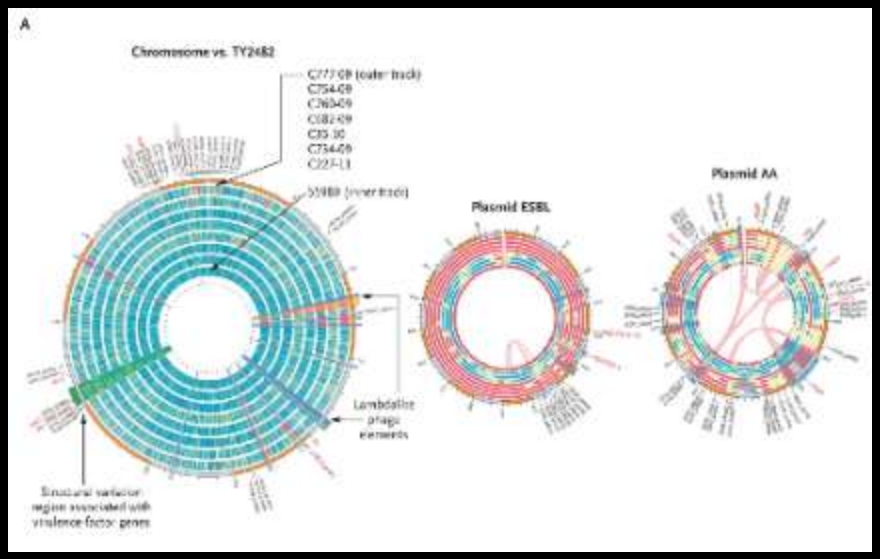
- robust triage
  - rationing
  - reassurance of "worried well"
  - quarantine decisions

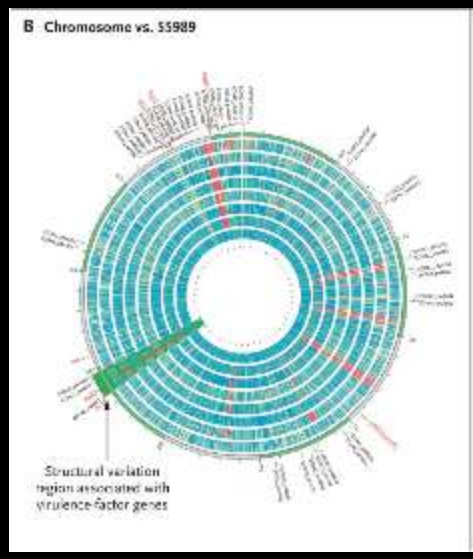
- real time disease surveillance data
- faster ID of incident evolution
- faster incident containment and exposure controls

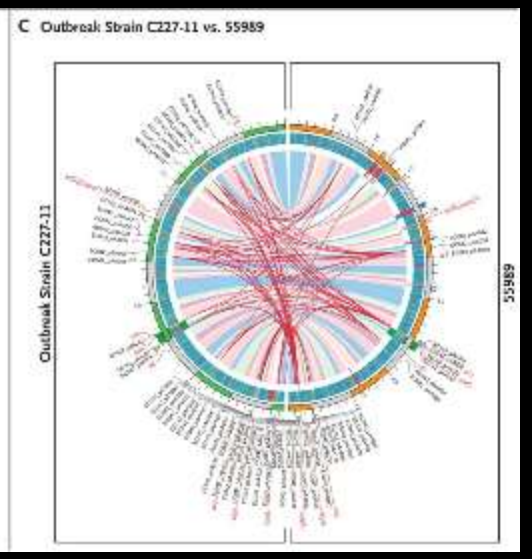
The Single Most Important Leverage Point For Rapid Mobilization of Resilient Responses to Epi-/Pandemics, Epizootics and WMD Bioterrorism

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)

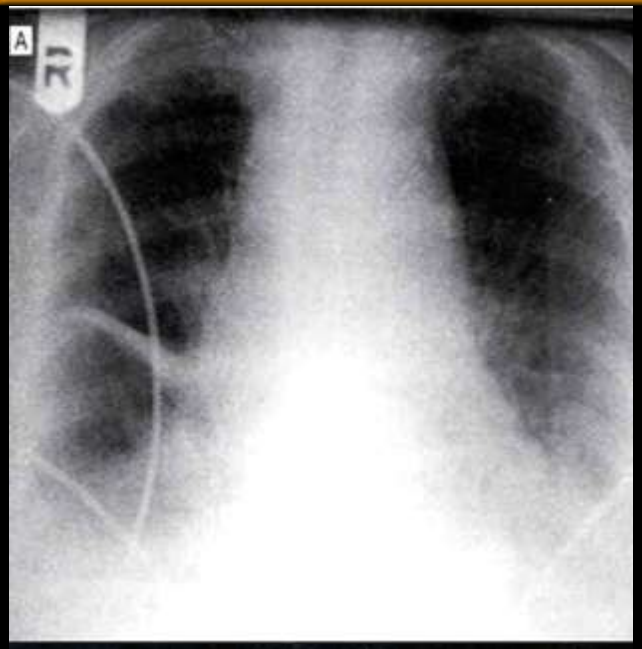
Preparedness: Building Resilient Systems

- 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

Education and Training

Diagnostic Accuracy

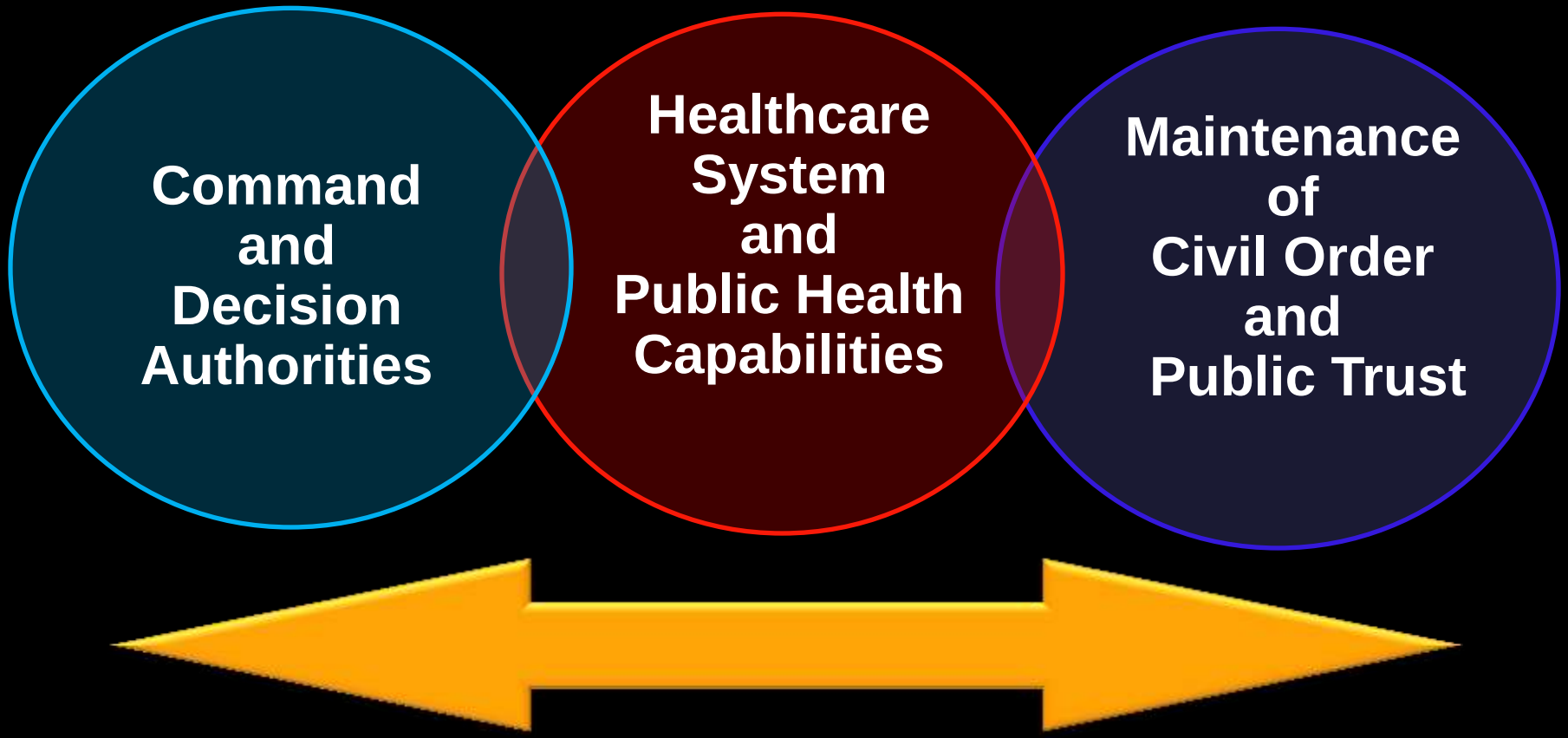


Infection Control

Availability of Therapy

Overload and Triage

The Three Core Components of Bioincident Management



- 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

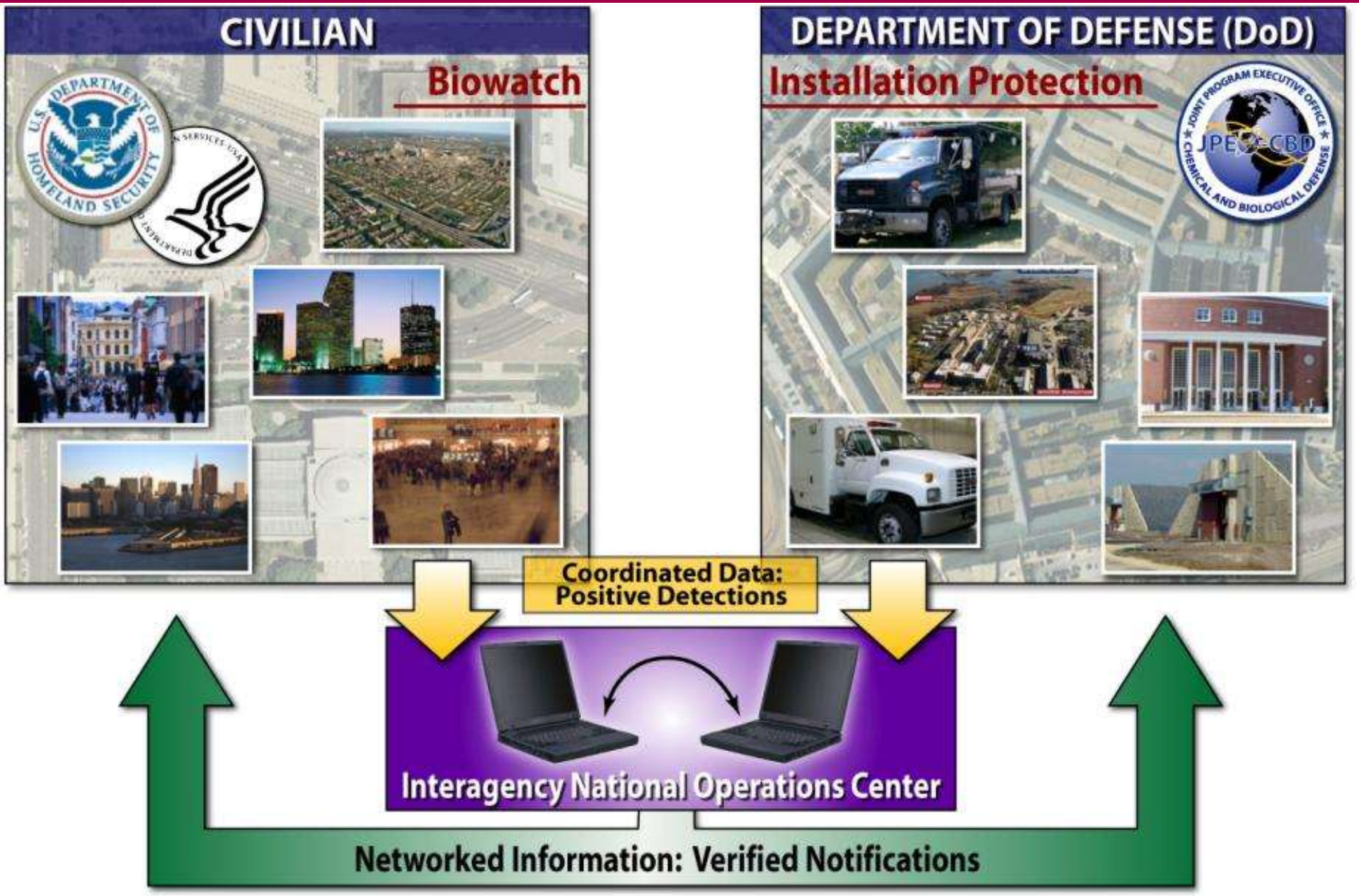
Medical Consequence Management of Major Bioincidents

Key Success Factors

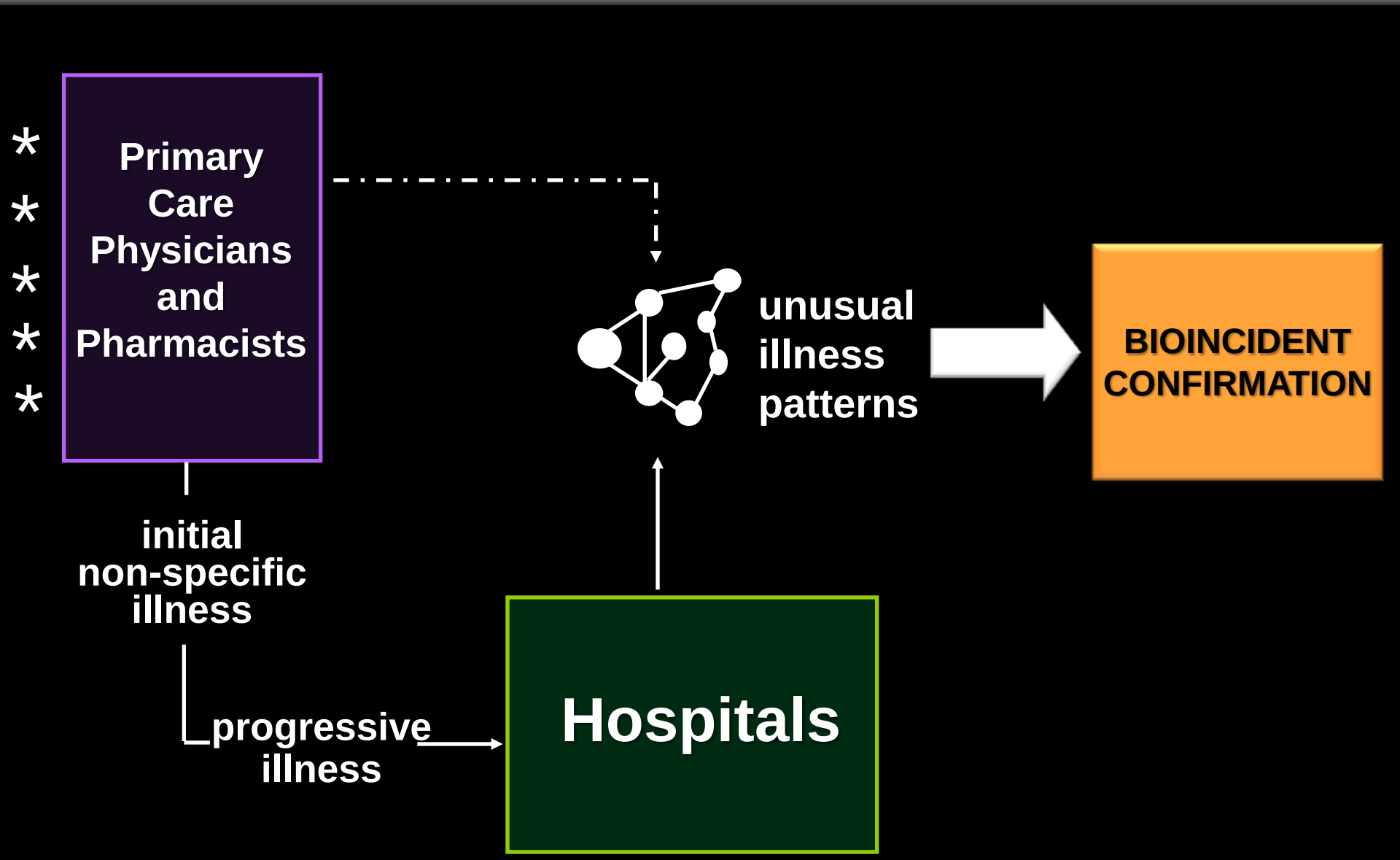
- tested disaster management plan
- responder training and education
- command structure
  - demarcated roles, responsibilities, authority
  - robust communication channels
- single source POC for key interfaces
  - ground zero staff (multiple ground zeros in CBW)
  - emergency services and first responders
  - medical/public health
  - politicians and inter-agency coordination
  - conventional media and social media

Building Resilience: Complex Systems-Based Integration of Diverse Functions and Organization

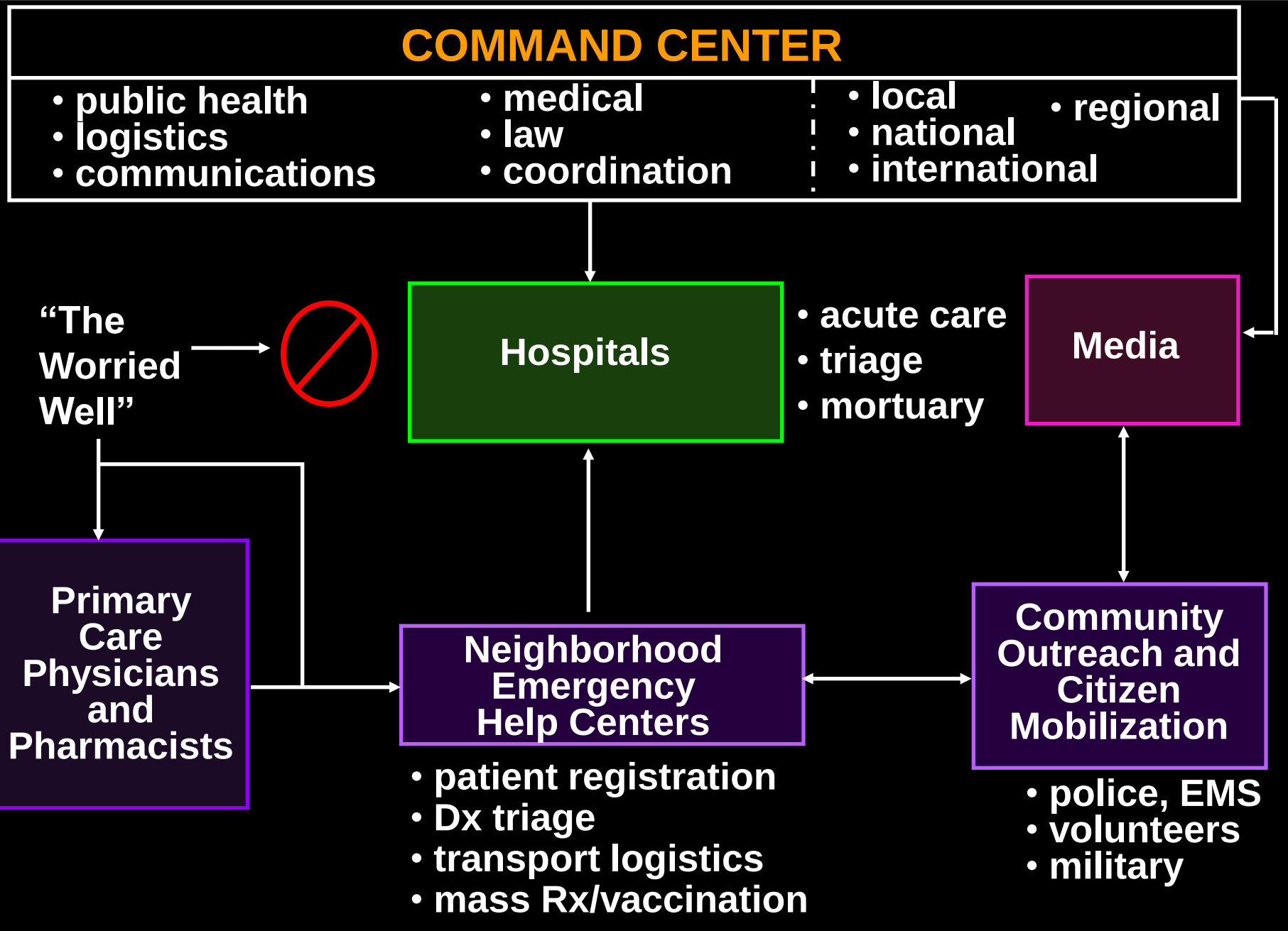
National Biomonitoring Notification Architecture



The Lag Phase in Bioincident Detection

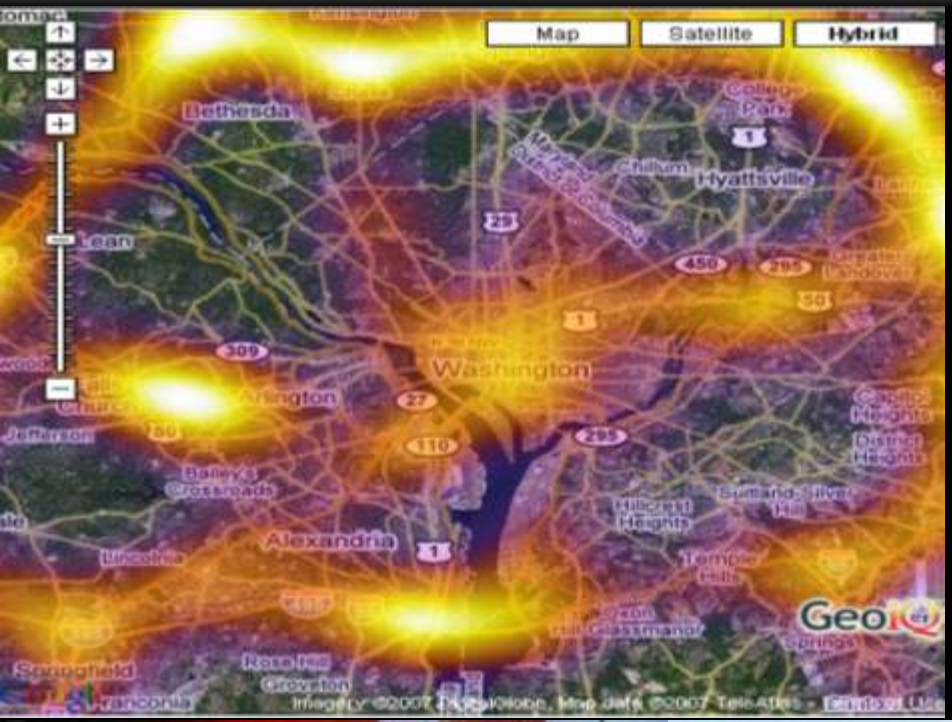


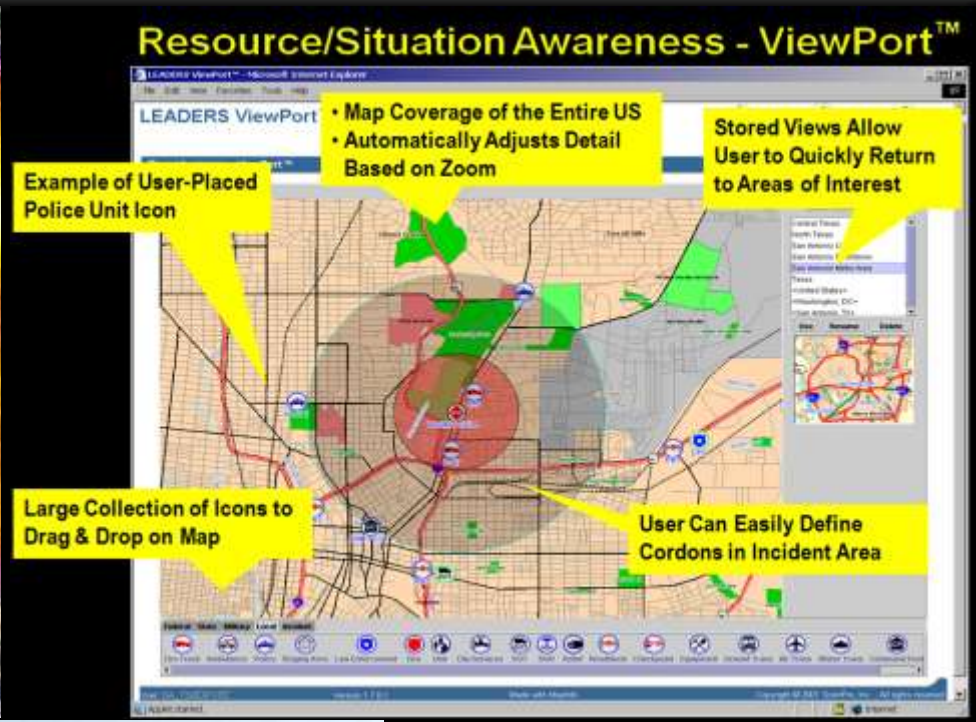
Consequence and Crisis Control in a Bioincident

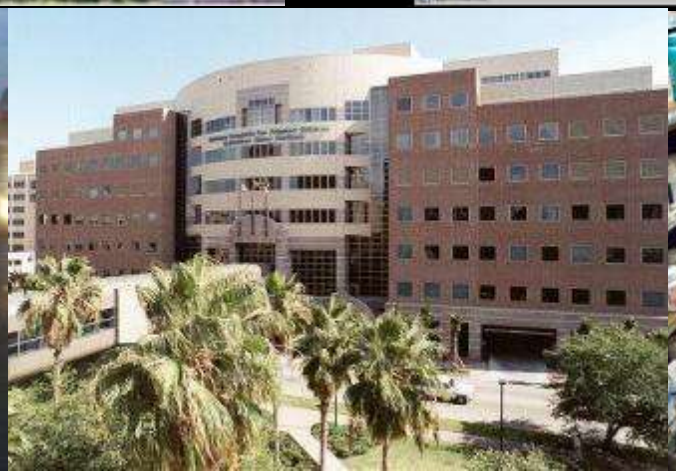


Cyber-Attacks and Vulnerable Infrastructure: Compromising Critical Systems

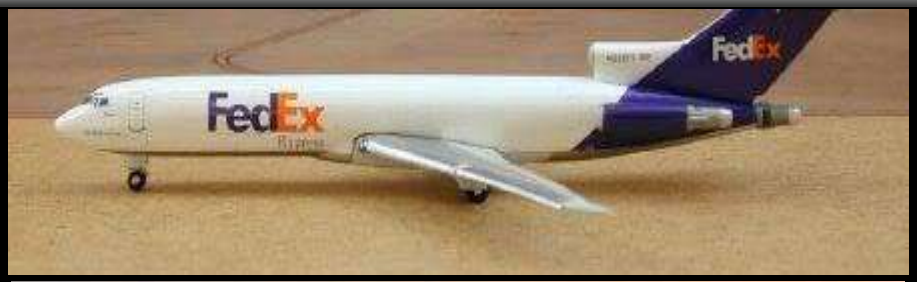
Use of GIS for Management of Population Movement, Healthcare Facilities and Supply Chains for Optimum Bioincident Control







Distribution of Medical Emergency Supplies for a Major Epidemic/Pandemic



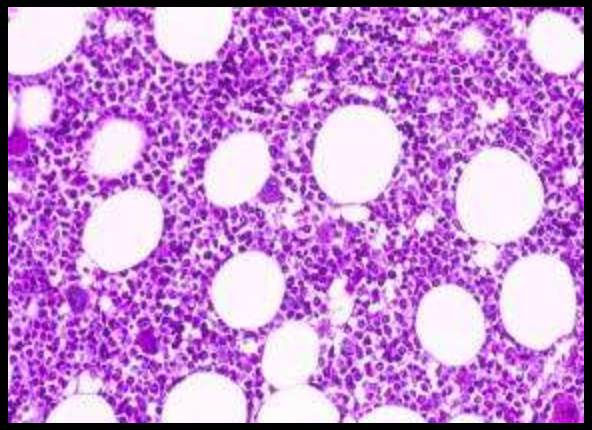
- pre-positioning for known threats: The Strategic National Stockpile
- rapid movement by commercial carriers
- managing political/public/media responses for bioincidents with limited or no Rx/vaccine options

Vulnerability of Global, National and Local Supply Chains in a Major Epidemic/Pandemic

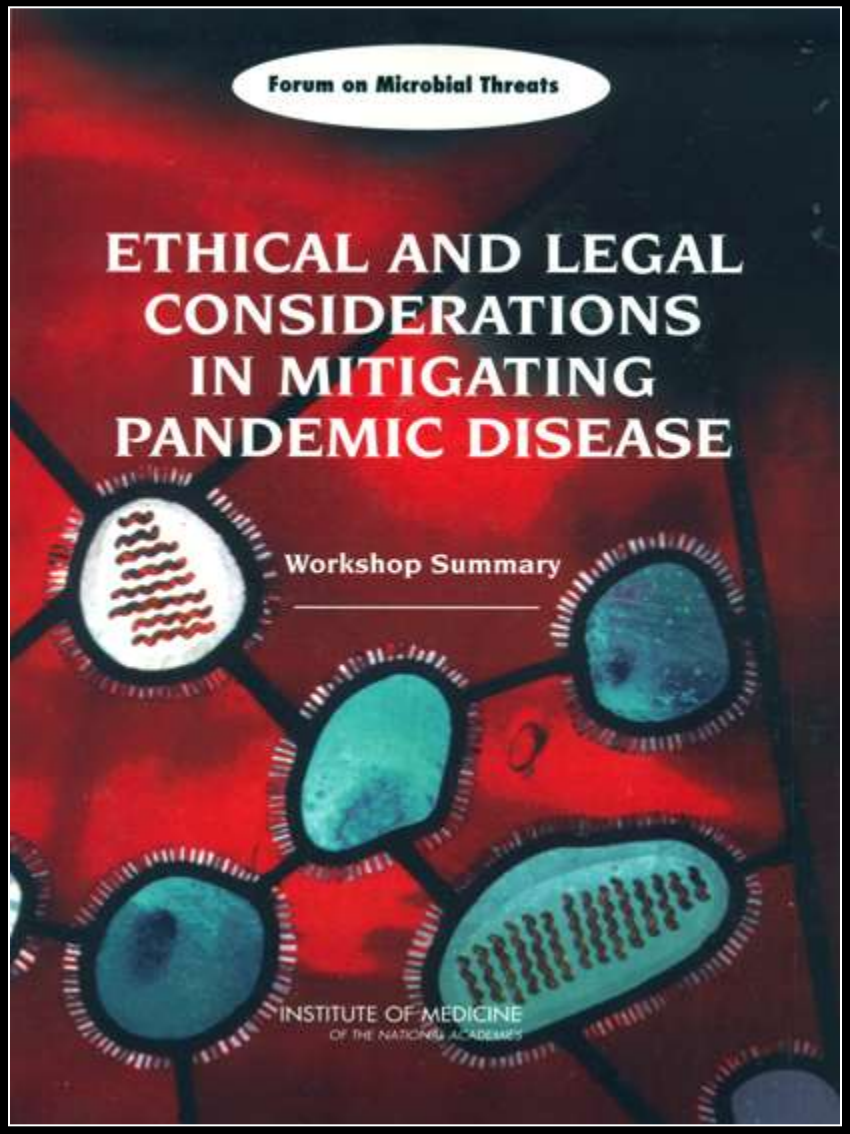
Medicines

- "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

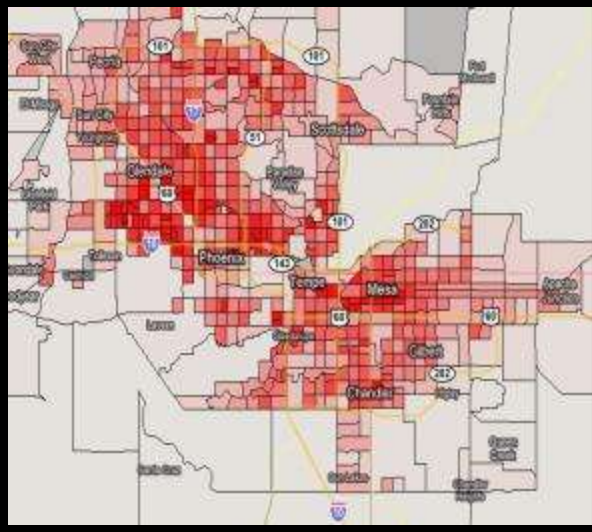
Pre-recorded Modules

Familiar (Trusted?) Face(s)

Credibility and Reality

Setting Examples to Limit Civil Disorder

Authoritative Leadership



Community Cooperation

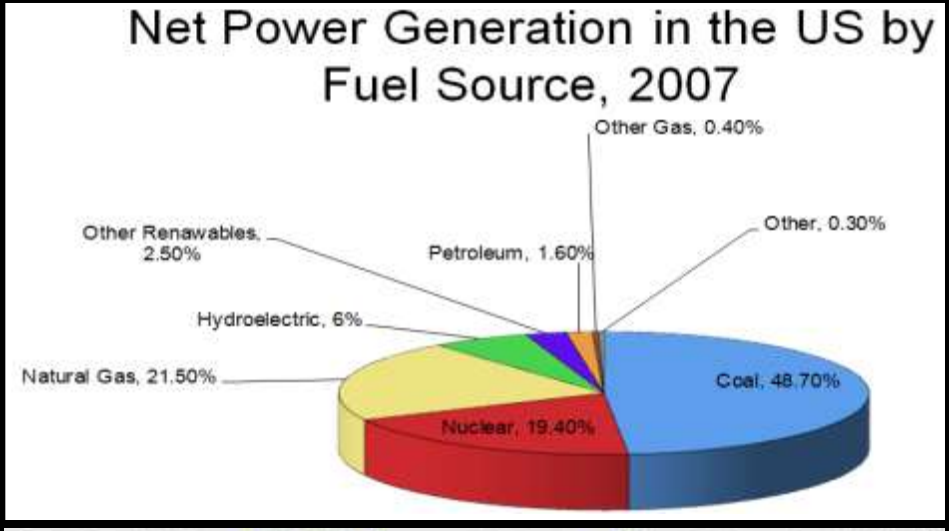
Informing the Public: A Critical and Unenviable Challenge

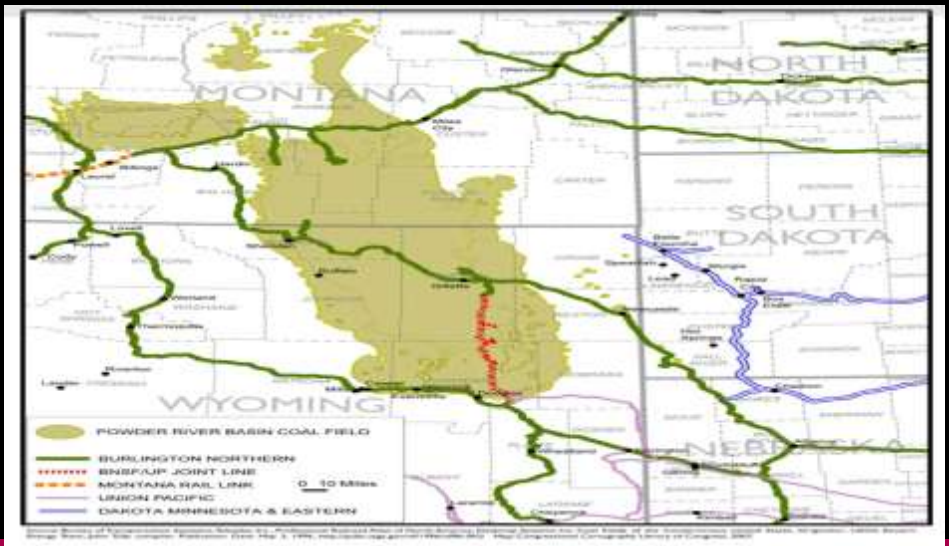
- media sensationalism and public panic
- pressure on governments to make illogical but politically expedient decisions
- in a severe outbreak the shock factor from level of fatalities will be unprecedented in modern peace times with unpredictable consequences
- unpredictable unilateral decisions by 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

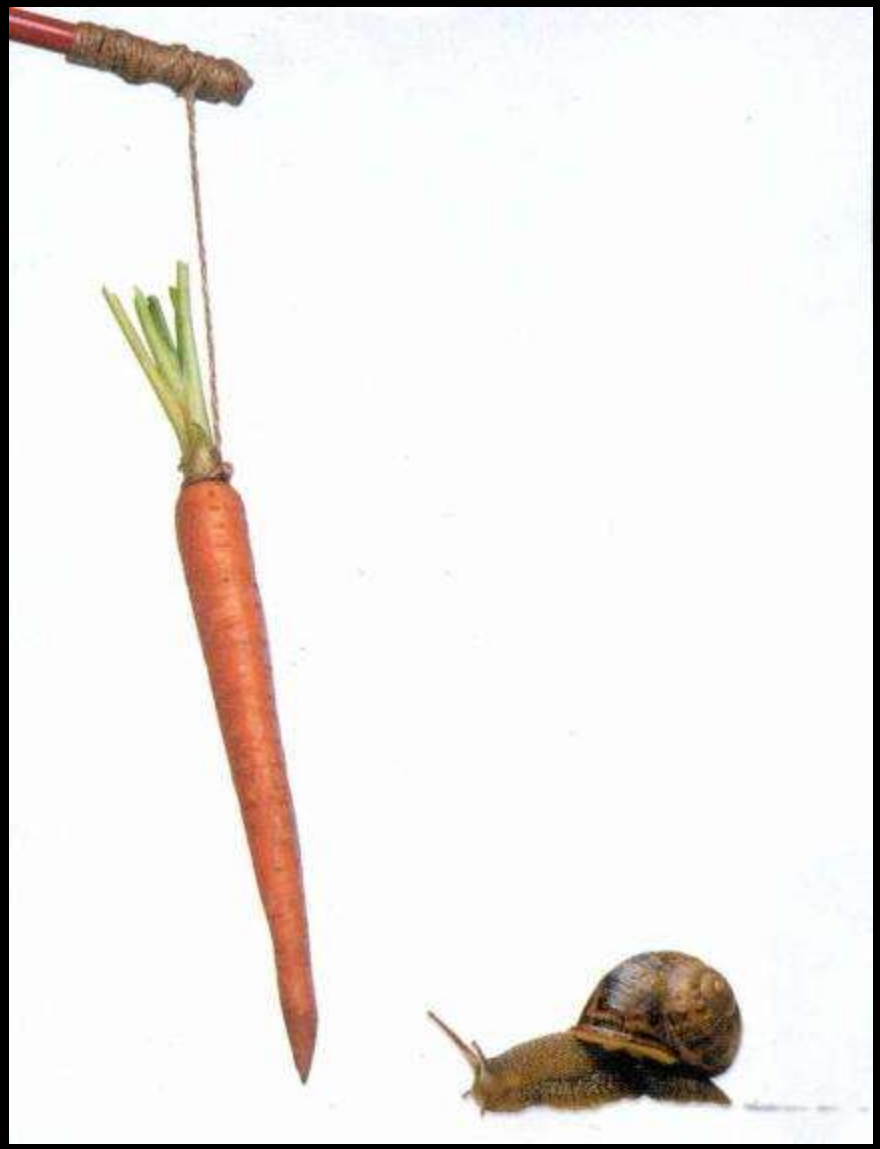




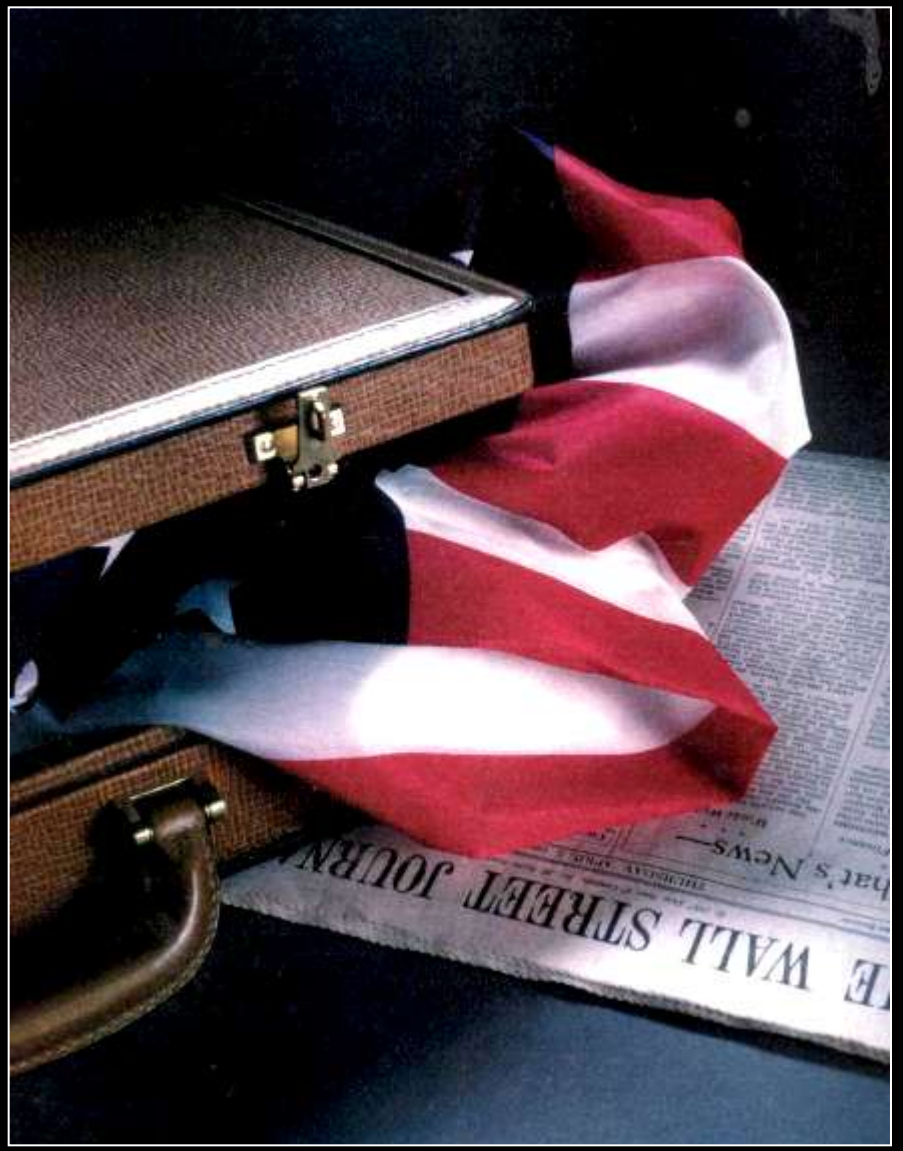
Protecting US Infrastructure

- 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

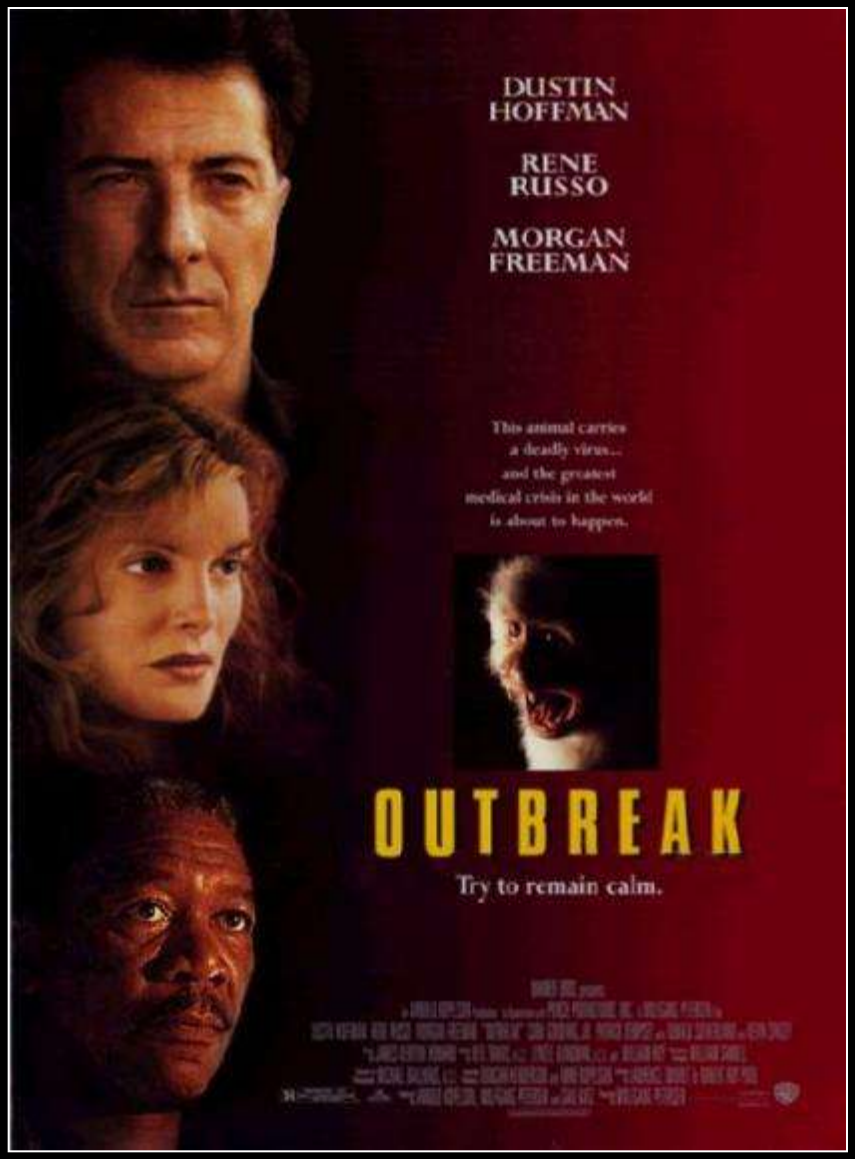
Who Pays for Preparedness?

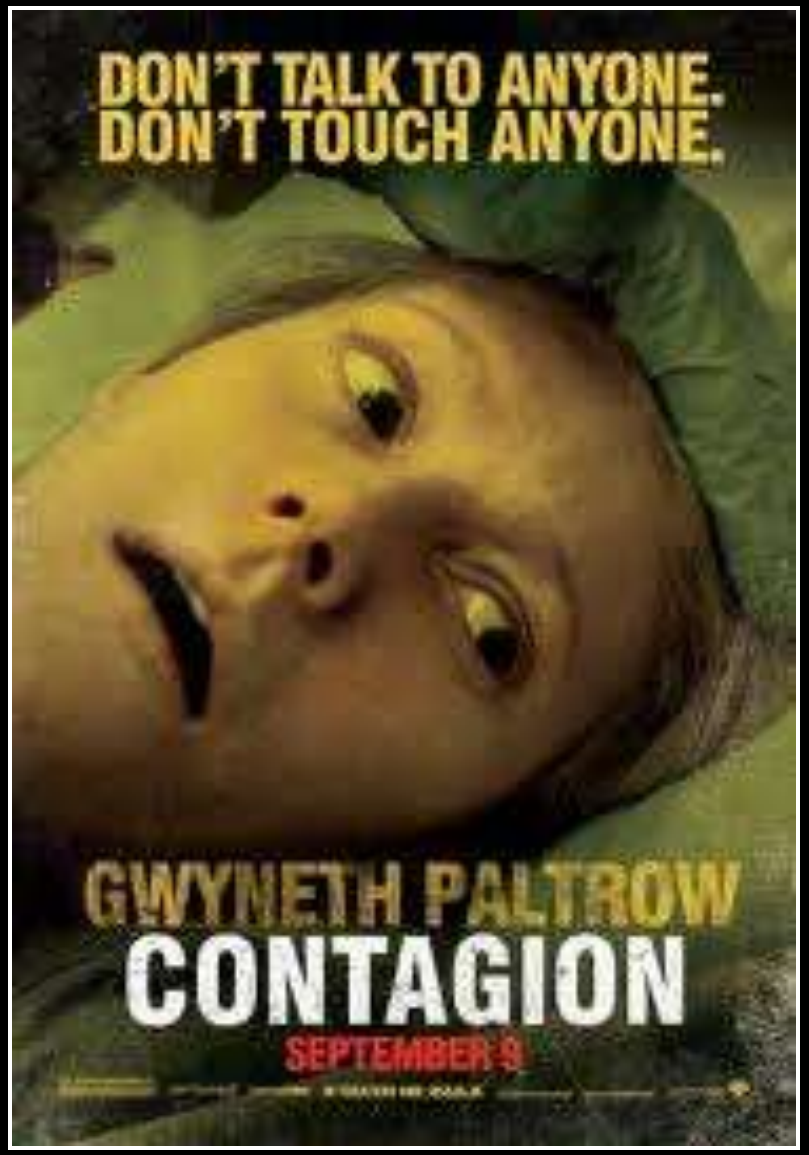


The Obligate Role of Private-Public Partnerships in Biosecurity Policy



….. 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)

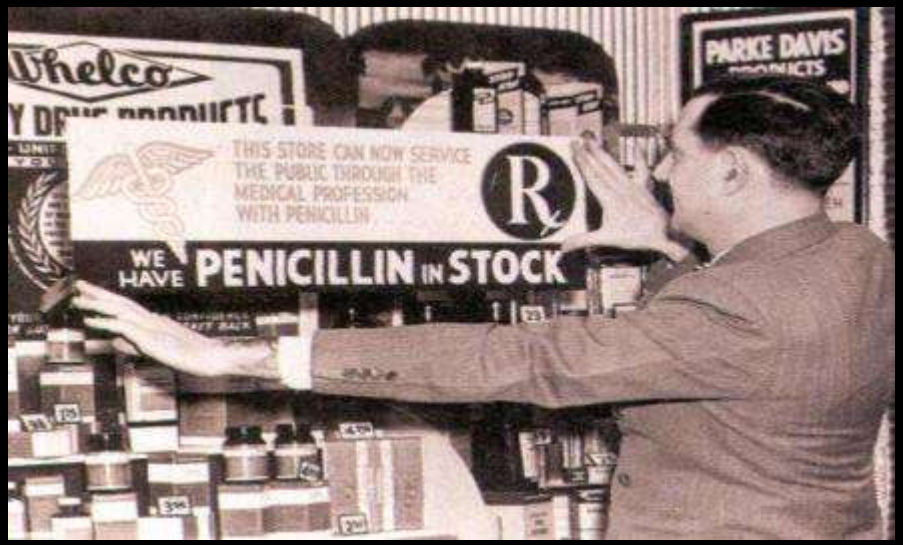
Drug Discovery and Development

"Fewer countries have discovered,
developed and registered drugs
to an international standard,
than have developed atomic bombs"

Chris Hentshel
Medicines for Malaria Venture
Lancet (2004) 363, 2198

Bad Bugs
and
Few New Drugs

Comfort and Complacency: The Enemies of Vigilance and Preparedness



Bad Bugs and Few New Drugs

NO ESKAPE!

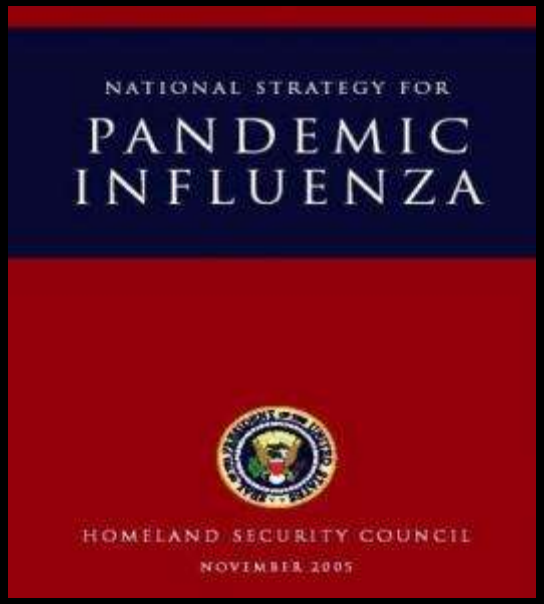
NO ESKAPE!: Resistant Bugs and Few New Drugs

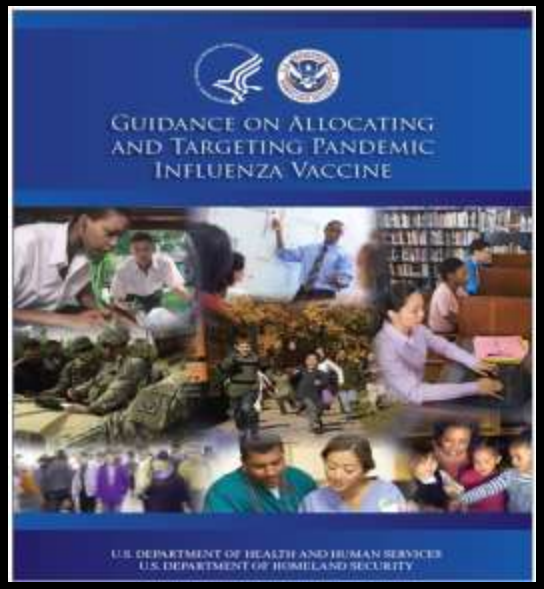
- increasing resistance in G^+ and G^- pathogens in hospital and community settings
- the **ESKAPE** pathogens
  - ***E**nterococcus faecium*
  - ***S**taphylococcus aureus*
  - ***K**lebsiella pneumoniae*
  - ***A**cinetobacter baumanii*
  - ***P**seudomonas aeruginosa*
  - ***E**nterobacter species*

The Valley of Dearth:
The Consequence of Declining R&D Investment in Antibiotic Discovery*

- 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

The Imperative for Innovation in Vaccine Production Technologies





"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

Public Response to H1N1 Vaccine for Pandemic Protection

“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

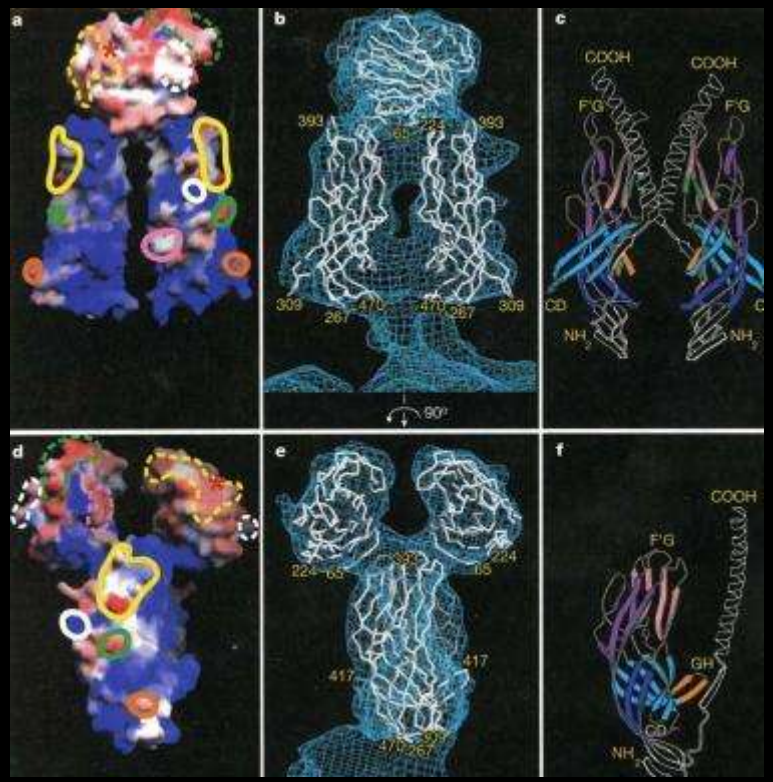
pan-vaccines

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

combating “Agent-X”

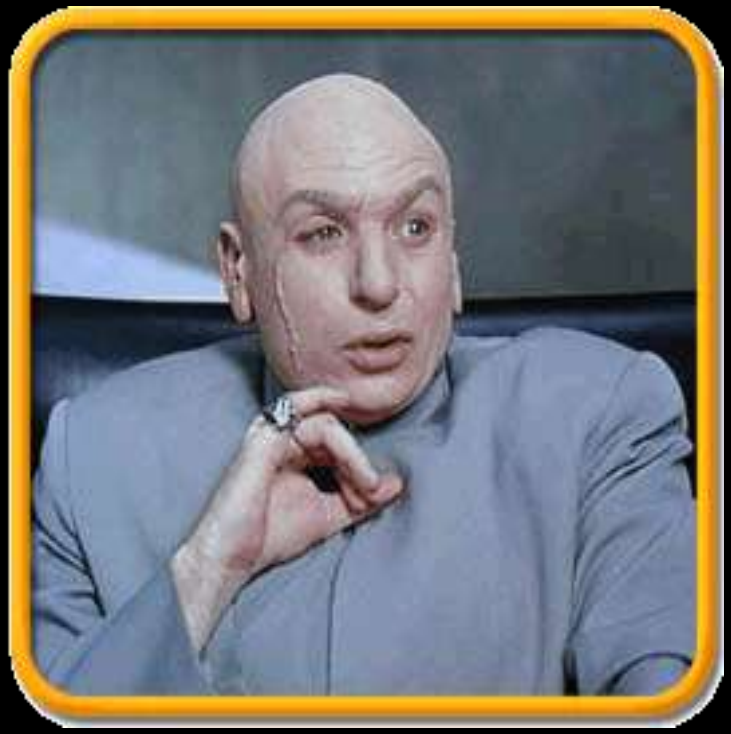
- rapid design and large scale production (weeks versus years) for protection against sudden emergence of an unprecedented pathogen (Agent-X)

Accelerated Manufacture of Vaccines



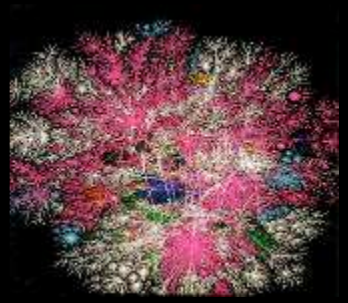
- convert vaccine production from a ‘biologics’ process to a ‘chemical’ manufacturing process
- reduce R&D cycle from 10-25 years to less than 1 year
- shorten production cycles run-time from 6-12 months to days/weeks

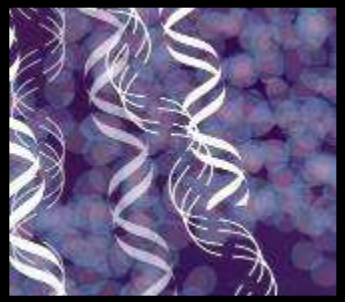
Future Trajectory Trends and Threat Expansion



New ‘Dual-Use’ Technologies

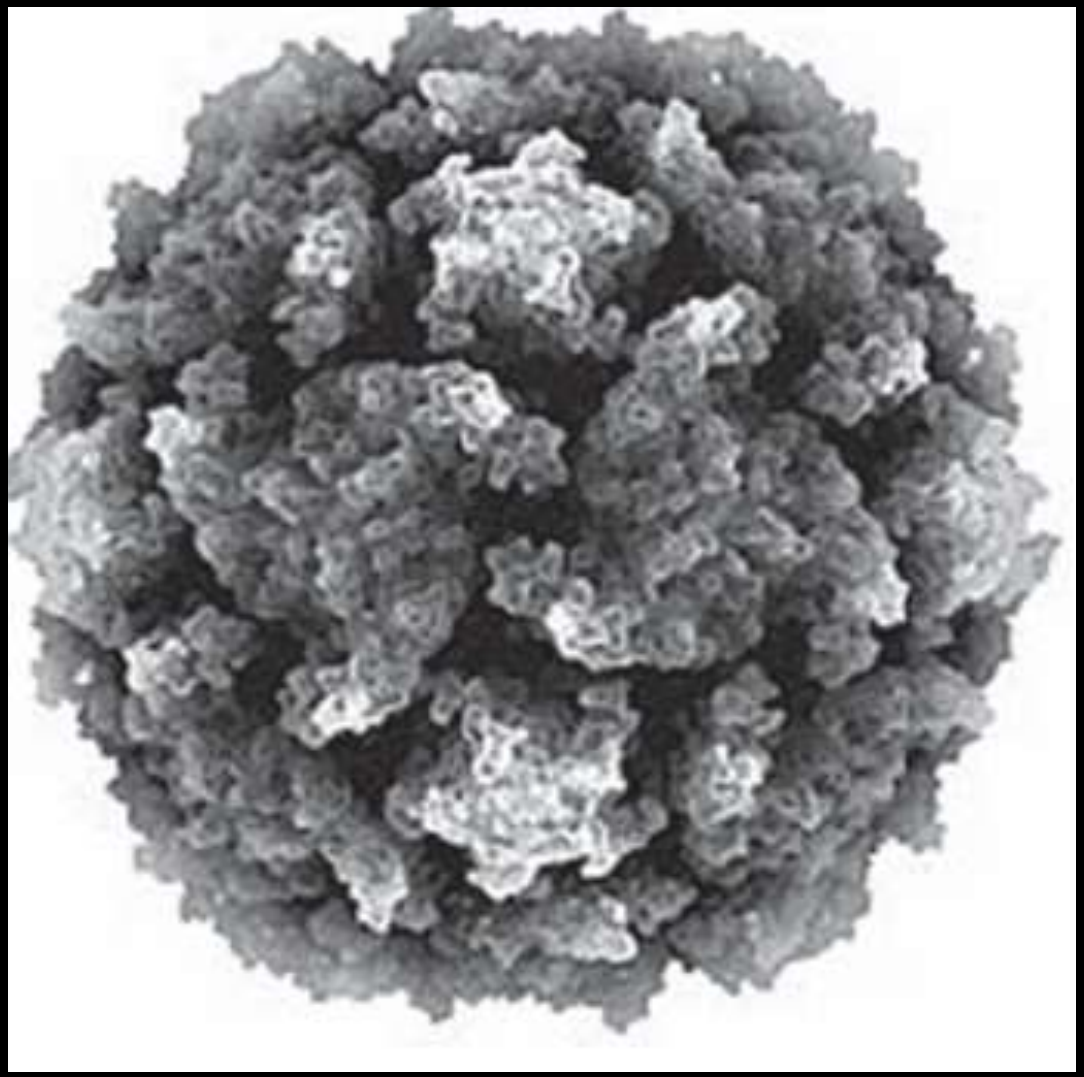
The Expanded Dimension of the ‘Bio’ Challenge





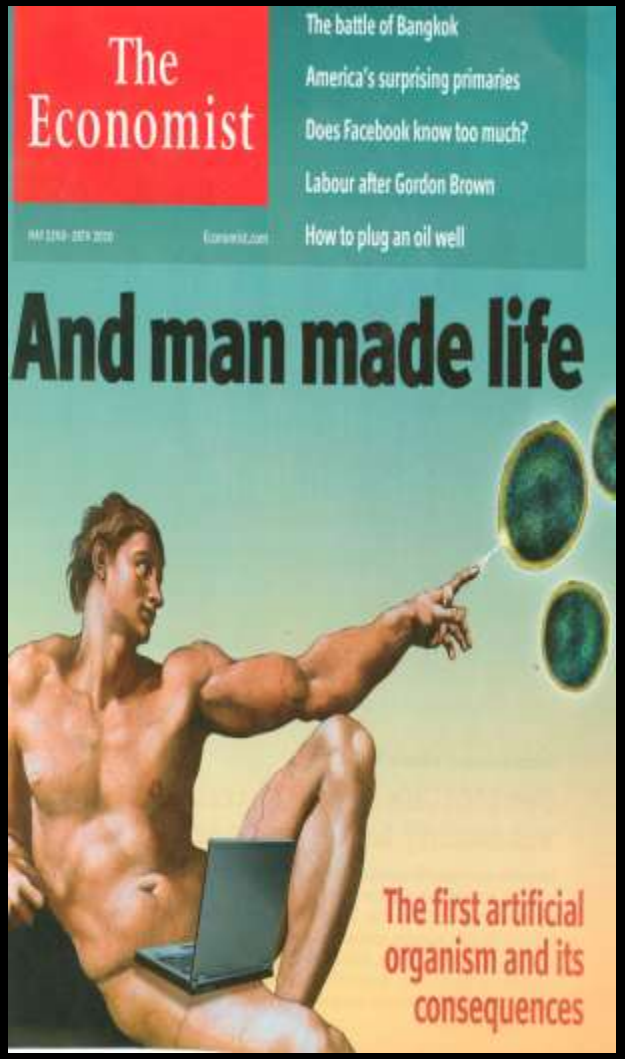
- thinking beyond ‘bio’ as just infectious agents (bugs)
- systems biology
  - targeted disruption of ANY body function
  - novel C and B threats
- synthetic biology
  - exploring biospace: designing new life forms
  - designer organisms to attack materials/infrastructure

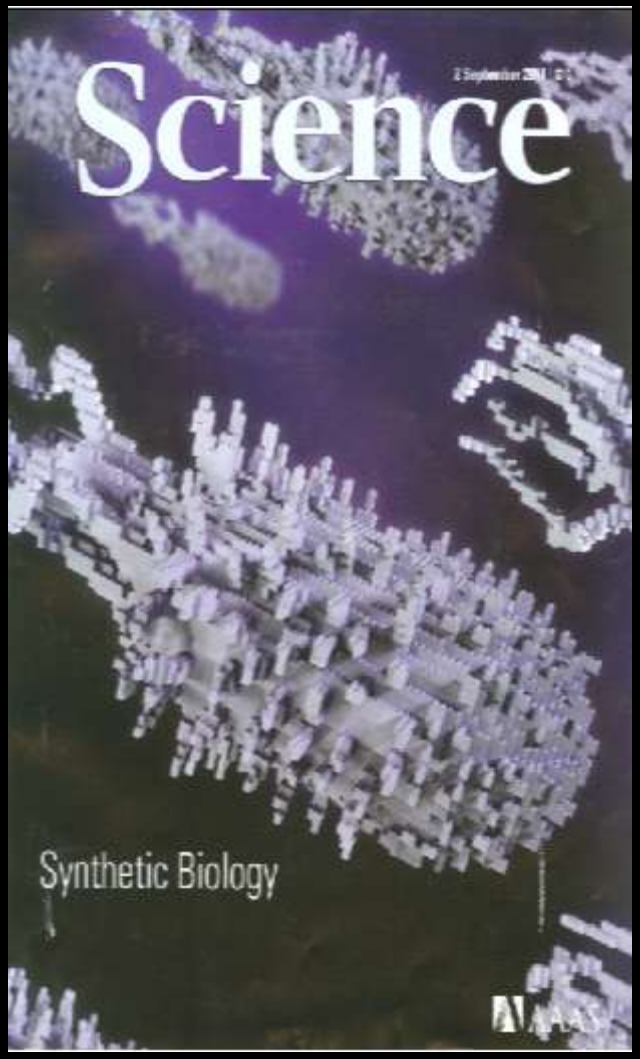
C332,652; H492, 388; N98, 245; O131, 196 P7, 501; S2,340
(a.k.a. poliovirus)



ATTGACTGCAA ……(design specifications)

Synthetic Biology





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**

Dual-Use Research of Concern (DURC)

Nature (2012) 482, 153

COMMENT

INFLUENZA Further explanation of the NSABB recommendations p.158

PRIMATES Imitation and social learning in apes p.159

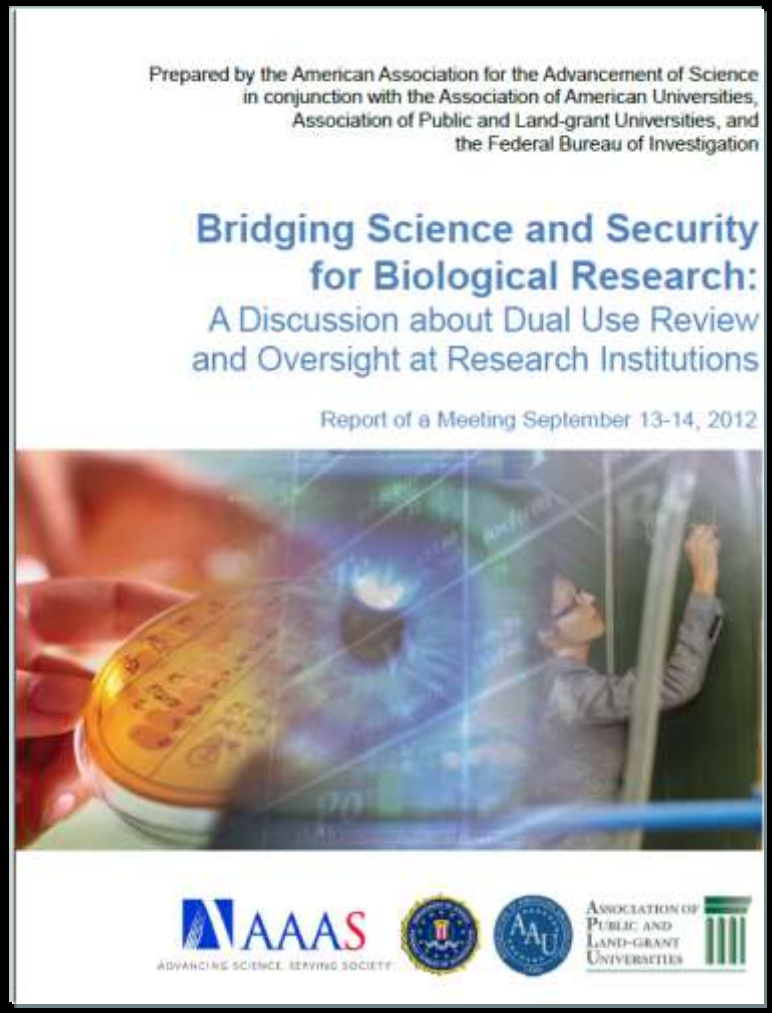
HISTORY John Dee's sweaving of scientific magic in the Elizabethan court p.160

CONSERVATION Trade in whale 'quotas' may be insufficient protection p.162

Pathogenic H5N1 avian influenza has led to the culling of hundreds of millions of birds. A human-transmissible form could have much worse consequences.

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

AAAS

ADVANCING SCIENCE, SERVING SOCIETY

Association of Public and Land-grant Universities

Dual-Use Research of Concern (DURC)

“Security is always excessive …..until it’s not enough”

The Fragmented Silos of USG: A Dangerous Vulnerability


OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE
UNITED STATES OF AMERICA


National Security Council


U.S. DEPARTMENT OF HOMELAND SECURITY


DEPARTMENT OF DEFENSE
UNITED STATES OF AMERICA

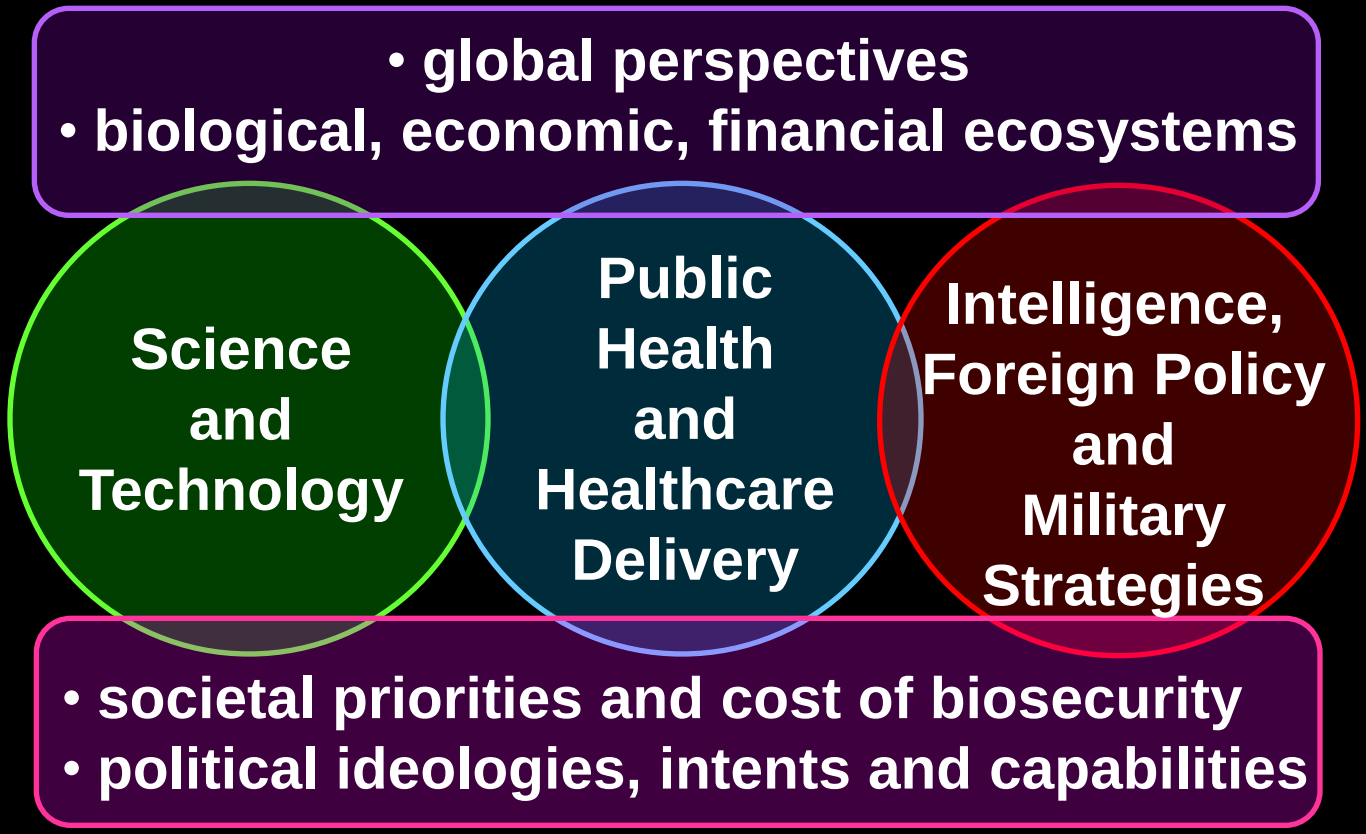

DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION


DEPARTMENT OF HEALTH & HUMAN SERVICES
USA


Central Intelligence Agency
Top
Secret


NO
ENTRY

Biosecurity:
A Classic Complex Systems Challenge



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**

Building Robust Defenses for Biosecurity

- 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)

Slides available @ http://casi.asu.edu/