

Biosecurity: a Multi-Dimensional Challenge of Escalating Complexity and Urgency

Dr. George Poste
Chief Scientist, Complex Adaptive Systems Initiative
and Del E. Webb Chair in Health Innovation
Arizona State University
george.poste@asu.edu
www.casi.asu.edu

Guest Lecture:
Stanford University Biosecurity Course
Stanford University School of Medicine
14 May 2014

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



Declared Interests:

- **Board of Directors: Monsanto, Exelixis, Caris Life Sciences**
- **Scientific Advisory Board: Burrill and Co., Synthetic Genomics, Univ. Michigan, Haplogen GmbH**
- **IOM Forum on Global Infectious Diseases**
- **USG Activities: DoD, DHS**

Biosecurity and Global Health: Understanding the Implications of Major Economic Disparities and Environmental Dislocations



Seeking Security in an Insecure World: The Military and National Security Calculus

Expanding Conflict Zones, Political Instabilities and Terrorism



**WMD
Proliferation**

**New Power
Centers**

**US Retrenchment:
Geopolitical/Fiscal**



The VUCA World

- **V**olatility
- **U**ncertainty
- **C**omplexity
- **A**mbiguity

The Biosecurity Triad

**Infectious
Diseases
of
Natural
Origin**

**Urbanization,
Environmental
and
Ecological Impacts
on
Disease
Emergence**

Bioterrorism



Biosecurity

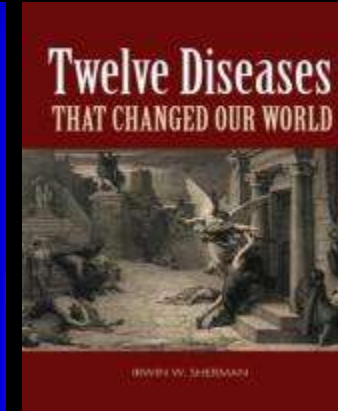
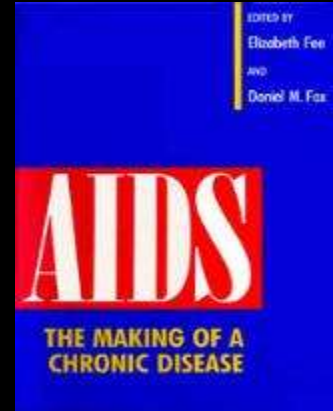
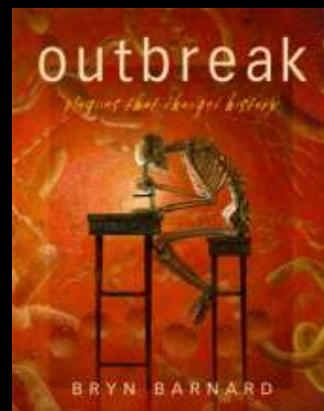
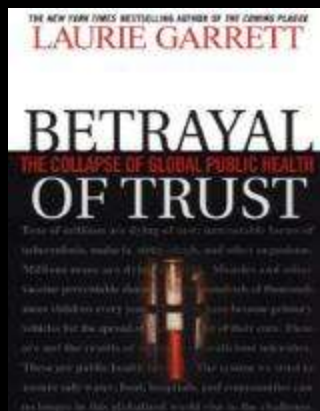
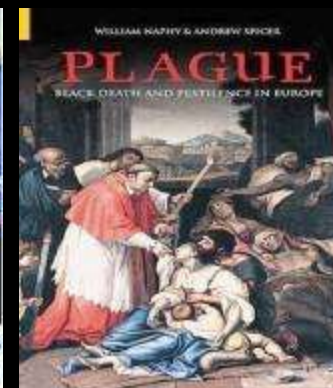
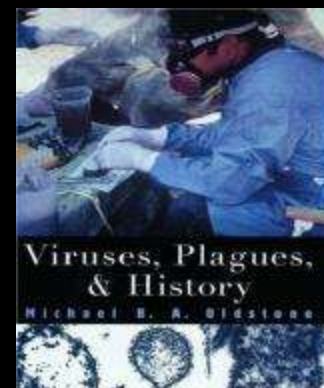
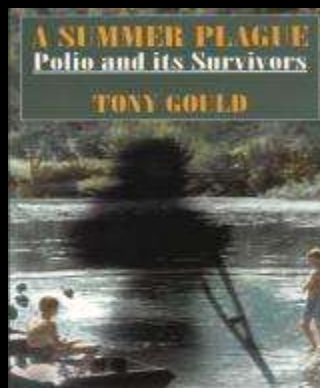
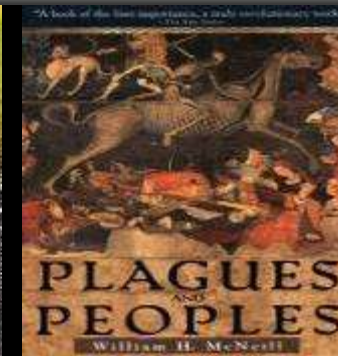
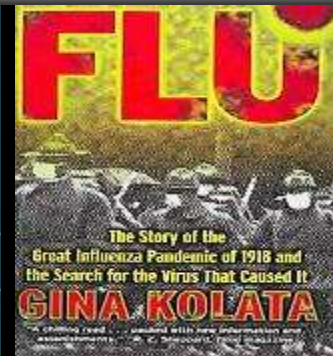
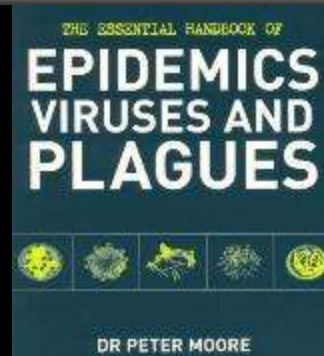
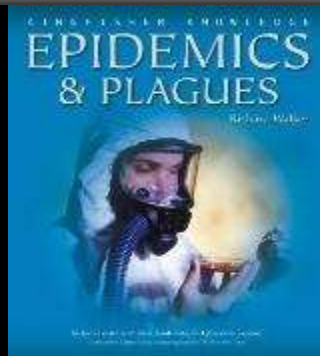
Today

- **bioterrorism: likely low probability, but high consequence**
- **natural infections: high probability, high consequence**
 - **old foes, resurgent foes and new EIDs**

2020 and beyond

- **new patterns of natural infections and therapeutic challenges**
- **bioterrorism**
 - **an expanded risk due to access to new technologies?**
- **synthetic biology**
 - **promise and peril: the ultimate dual-use technology**

Infectious Disease: A Powerful Force in Human Evolution



Terrorism and The New Calculus of National Security and Foreign Affairs





TOM BROKAW
NBC TV
30 ROCKEFELLER PLAZA
NEW YORK NY 10112

1011240002

09-11-01

THIS IS NEXT

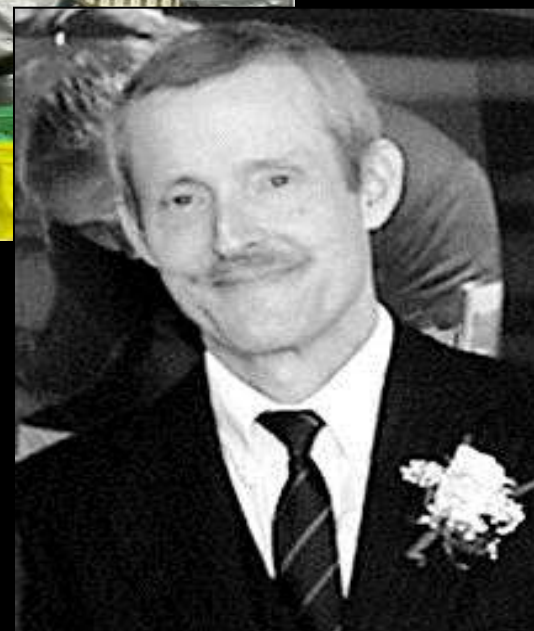
TAKE PENACILIN NOW

DEATH TO AMERICA

DEATH TO ISRAEL

ALLAH IS GREAT

**"I will show you fear
in a handful of dust"
T.S. Elliot**



**THE SOVIET
BIOLOGICAL
WEAPONS
PROGRAM**



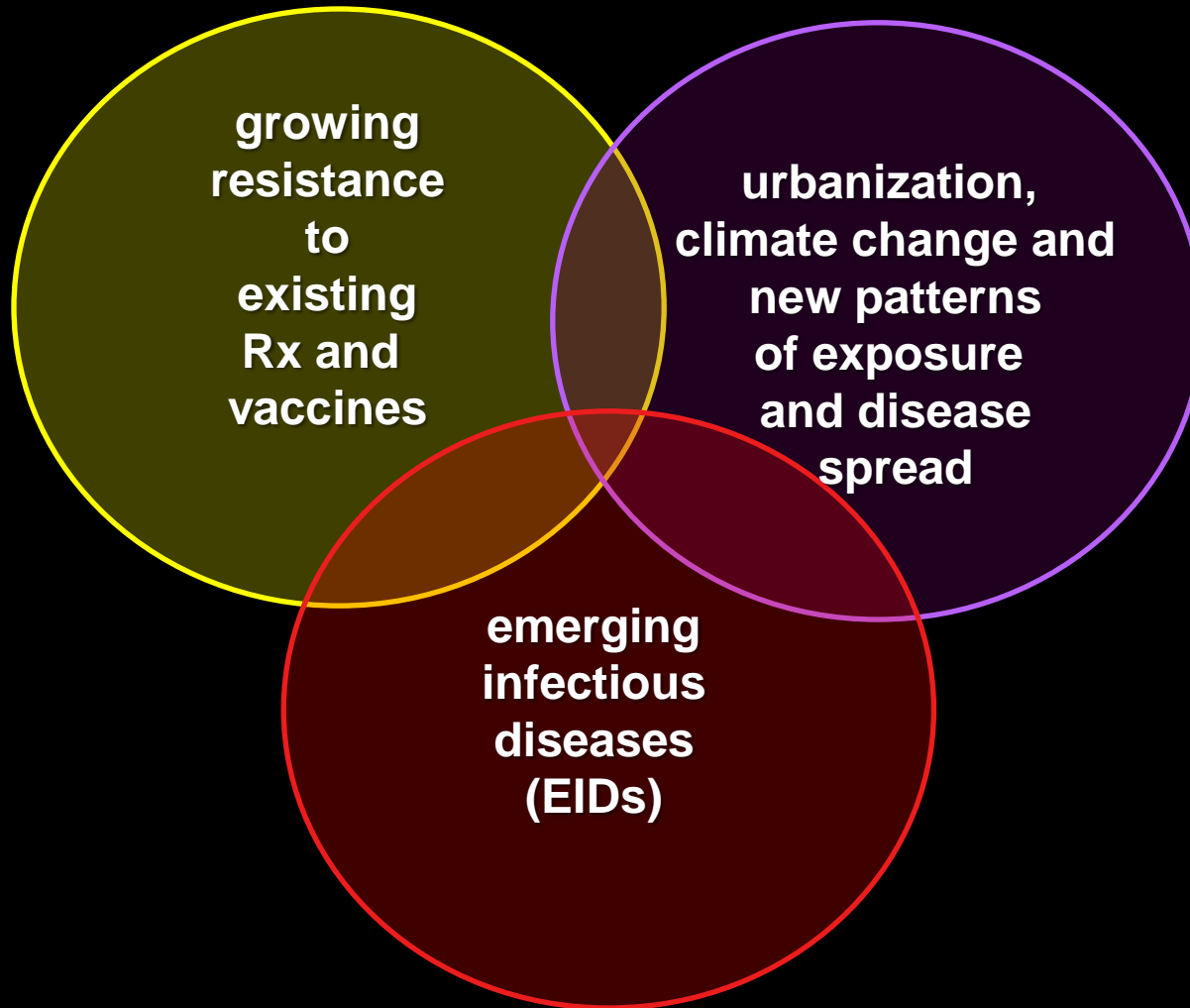
A HISTORY

MILTON LEITENBERG

RAYMOND A. ZILINSKAS

**Preparedness:
The “All Hazards” Challenge
and
Building Resilient Systems**

Outpacing Infectious Diseases



The Global Public Health Challenge Posed by Rapid Urbanization in Developing Countries

High Disease Transmission



Lack of Safe Water



Bush Meat Food Chain

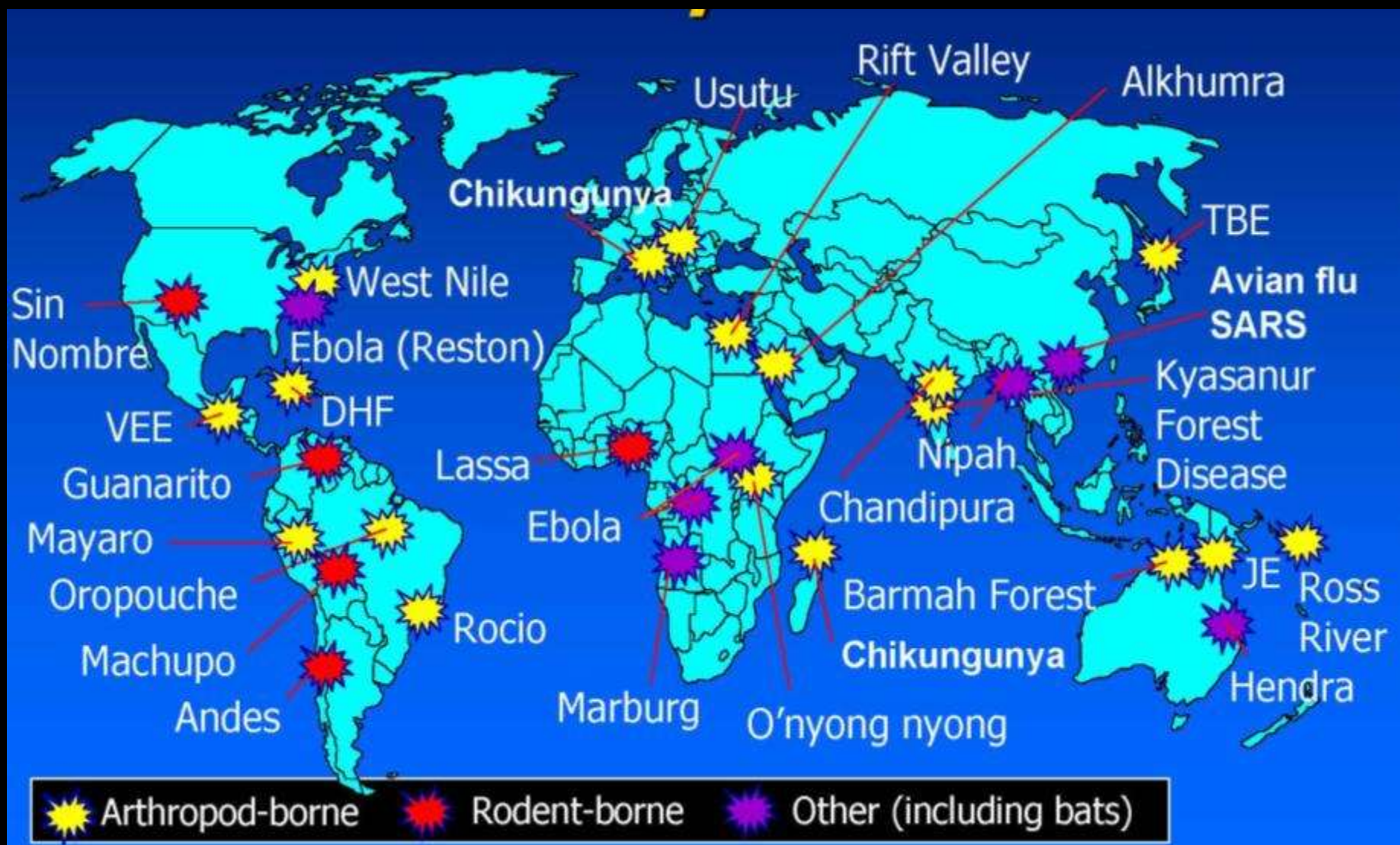


Major Deficits in Health Infrastructure



Expanded Eco-niches and Increased Zoonotic Risks

Emerging Infectious Diseases (EIDs)

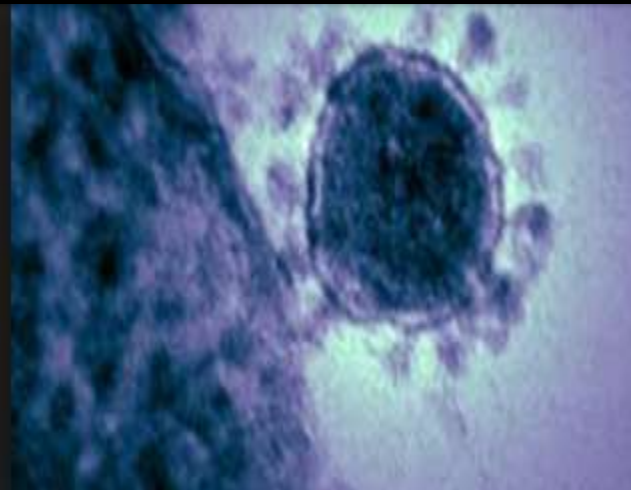


Human Coronaviruses

Emergence of SARS-CoV (PRC 2003)



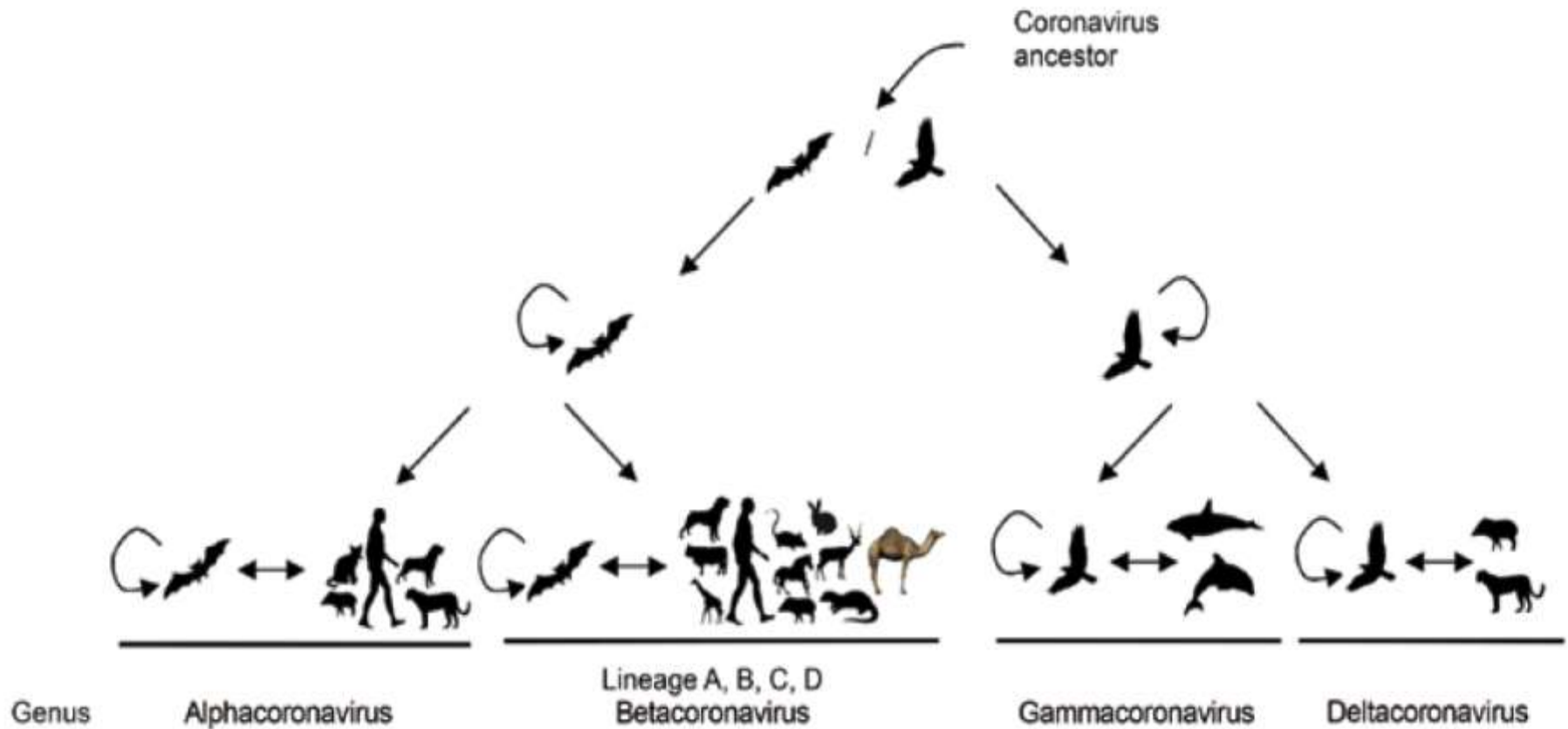
Emergence of MERS-CoV (KSA 2012)



Understanding Animal to Human Transmission



Evolution of Coronaviruses from Ancestors in Bat and Avian Hosts

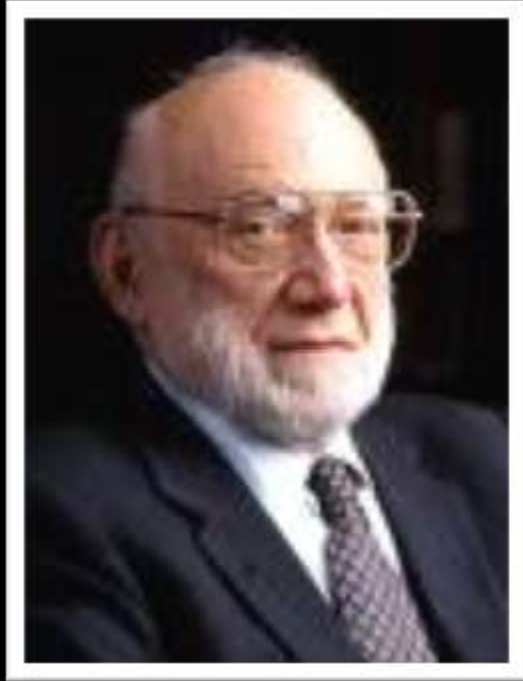


From: P. C. Y. Woo et al. (2014) EID 20, 560

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 future of humanity and microbes
will likely evolve as episodes
of our wits versus their genes”**

**Dr. Joshua Lederberg,
Nobel Laureate
Science (2000) 6, 427-30**

The Evolving Nature of Human Infectious and Parasitic Diseases

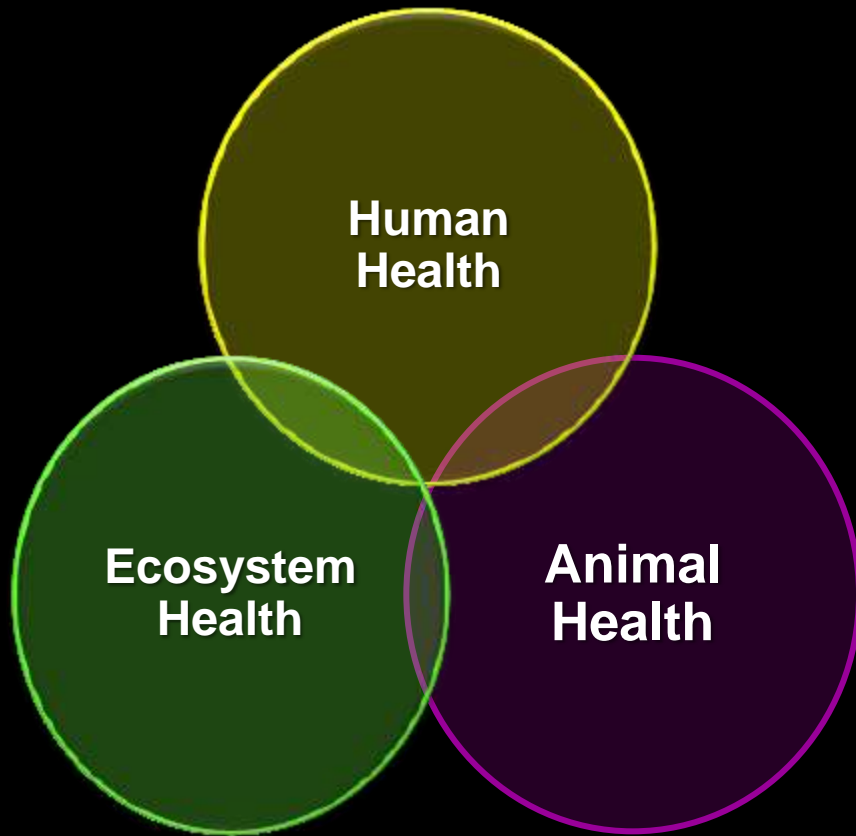
1407 species of human pathogens

- 538 bacteria
 - 57 protozoa
 - 60% are zoonoses
 - over 70% zoonoses arise from interactions with wildlife
 - Emerging Infectious Diseases (EIDs)
 - 58 in last 25 years
 - viruses significantly over-represented
 - RNA viruses most variable and rapidly changing
 - helminths under-represented
- 208 viruses
 - 287 helminth worms
 - 317 fungi

One Health

**The Need for a Holistic View of
Host-Pathogen Ecology**

“One Health”: The Rationale for Integration of Historically Separate Domains and Responsibilities



- **urbanization of DCs and emergence of new zoonotic threats**
- **food chain as increasing source of disease risks**
- **enhanced agricultural productivity for food security to support global population growth**
- **economic impact of agricultural disease on trade, development and resources/production footprints**

Preparedness: Building Resilient Systems

- are the risks known and analyzed?
- are there actions for meaningful intervention?
 - tractable, measurable
- if not, how can these be developed and implemented (resources, infrastructure, logistics, cost)?
- what are the principal risks and obstacles to success? (technical, economic, political, social, legal)
- how are these barriers being addressed and, if not, what is needed to reduce/eliminate them? (vulnerability assessment and mitigation)



Global Disease Surveillance



EMERGEncy ID NET



Public Health Department's Surveillance



U.S. Influenza Sentinel Provider Surveillance Network



Quarantine Activity Reporting System (QARS).



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



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

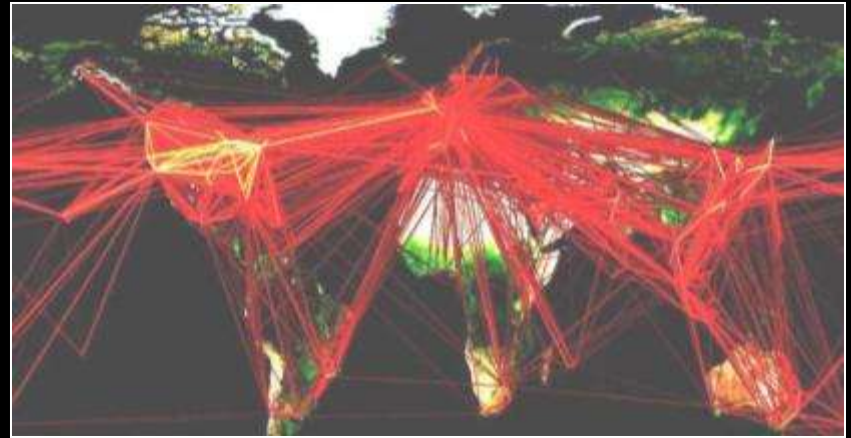
The Super Vector



**World Container
Traffic Doubled
Since 1997**



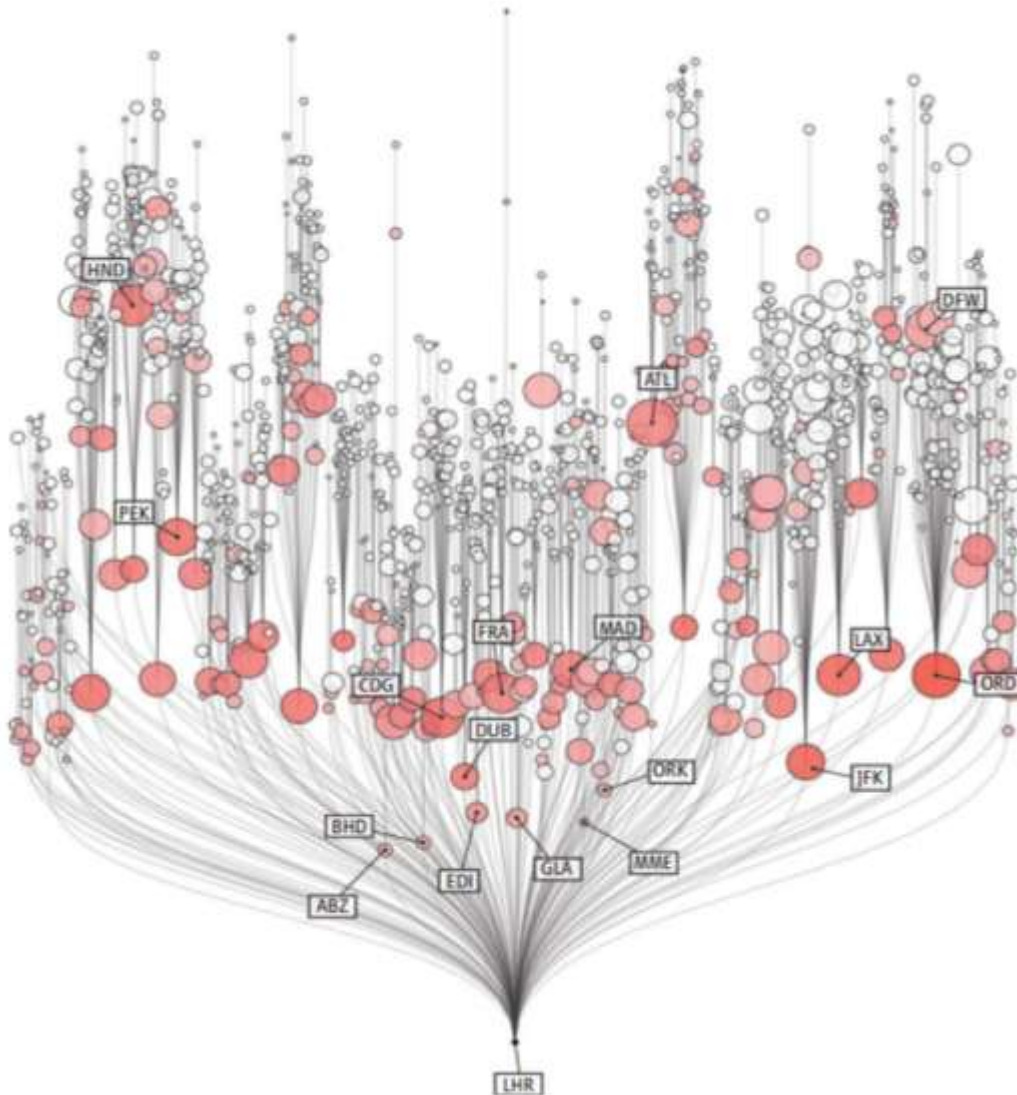
Billion Cross-Border Travelers



Global Food Networks



Coming to an Airport Near You:



**Modeling Airport
Connectivities, Traffic
and Distance
Relationships and
Implications for
Epidemic Spread via
the Global Aviation
Network**

**From: A. R. McLean
(2013) Science
342, 1330**

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**

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**

Real-time Remote Health Status Monitoring: The Value of Mobile Devices and Sensors



- geolocation data (where)
- temporal information (when)
- contextual information (what)
- improved decision support (action)

**The Public Health, Economic and Political Challenges
of a Major Bioincident**

**Preparedness for Managing Substantial
Societal Dislocations**

Silos Subvert Solution

Detection of a Major Bioincident

Not A Hazmat or Wide Area Sensor Network Solution



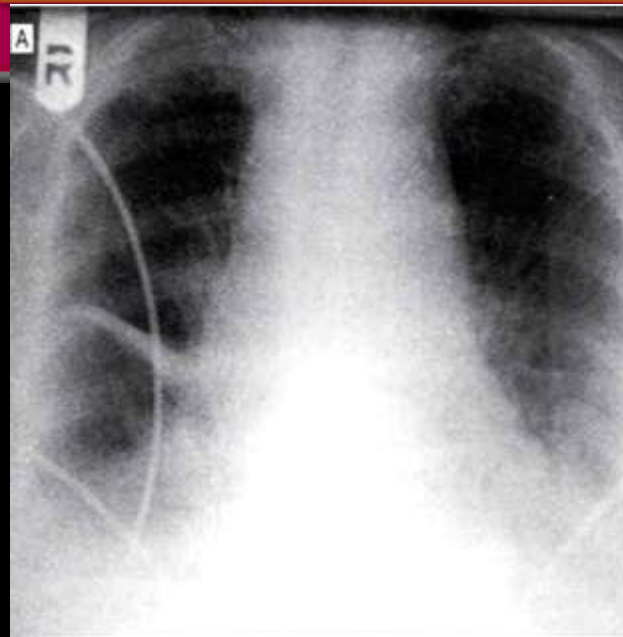
Emergency Rooms and Farms Will be the Front Line



Education and Training



Diagnostic Accuracy



Infection Control

Availability of Therapy

Overload and Triage

Earlier Diagnosis and Intervention Saves Lives

Improved speed, breadth and accuracy of clinical diagnosis



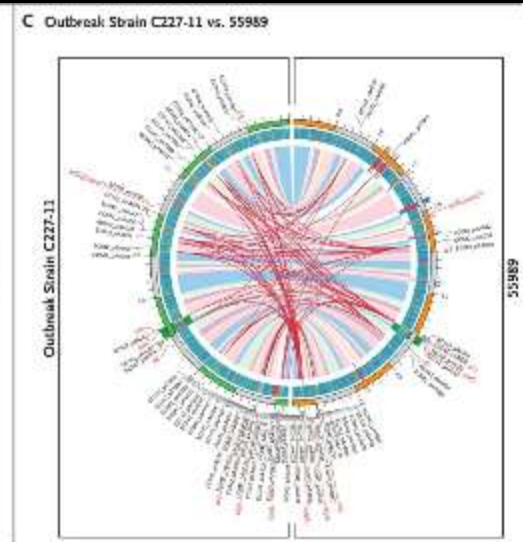
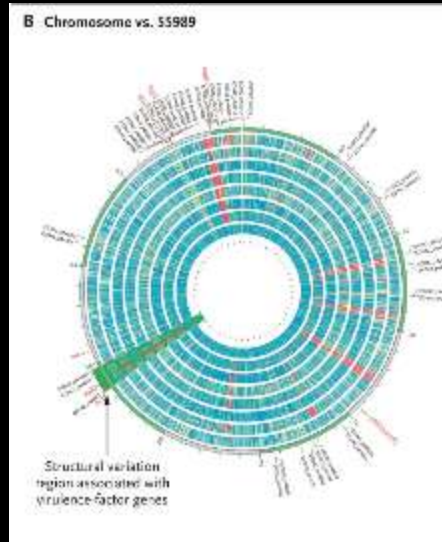
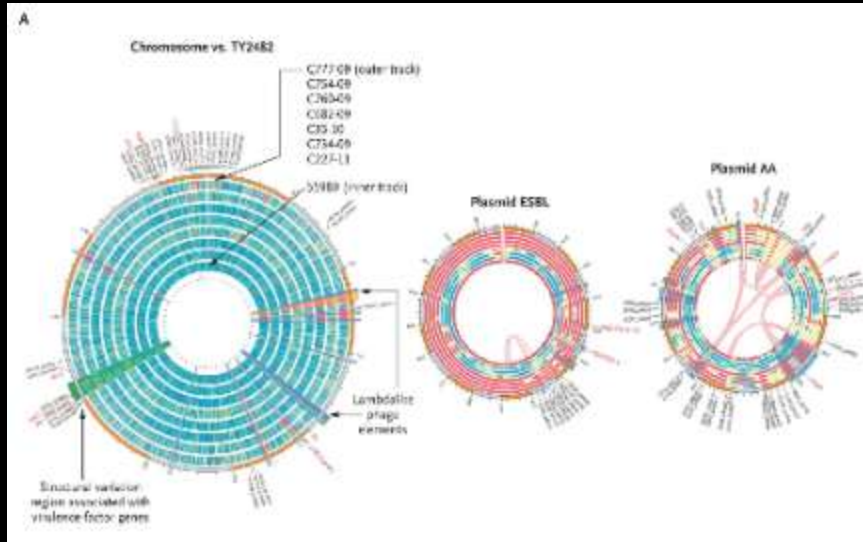
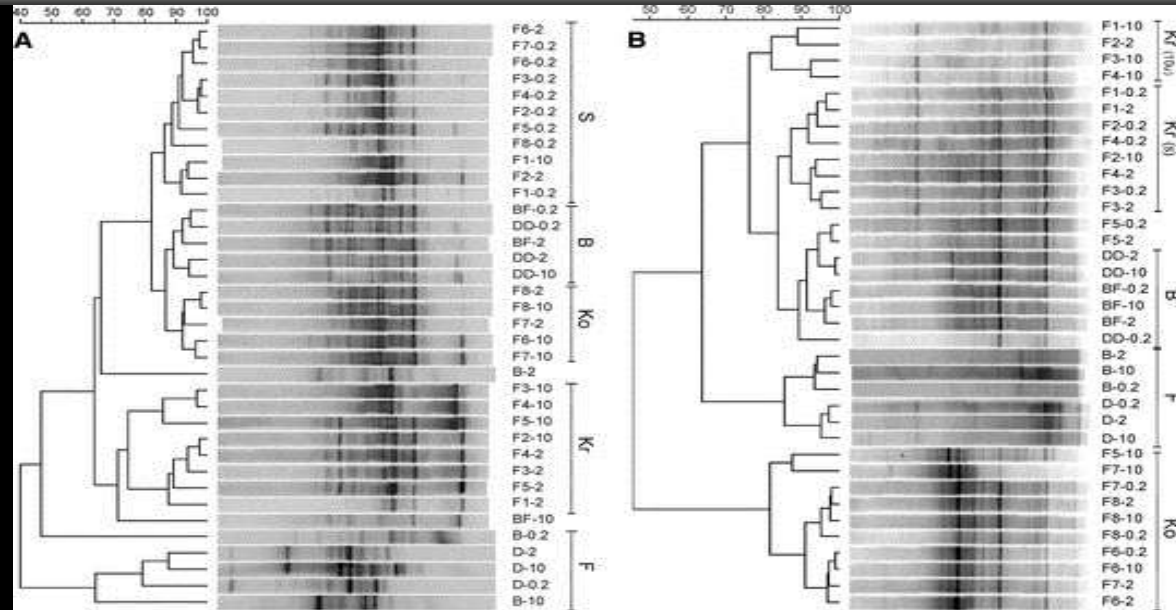
- faster Rx
- accurate Rx
- prophylactic Rx for incident personnel
- robust triage
 - rationing
 - reassurance of “worried well”
 - quarantine decisions
- real time disease surveillance data
- faster ID of incident evolution
- faster incident containment and exposure controls



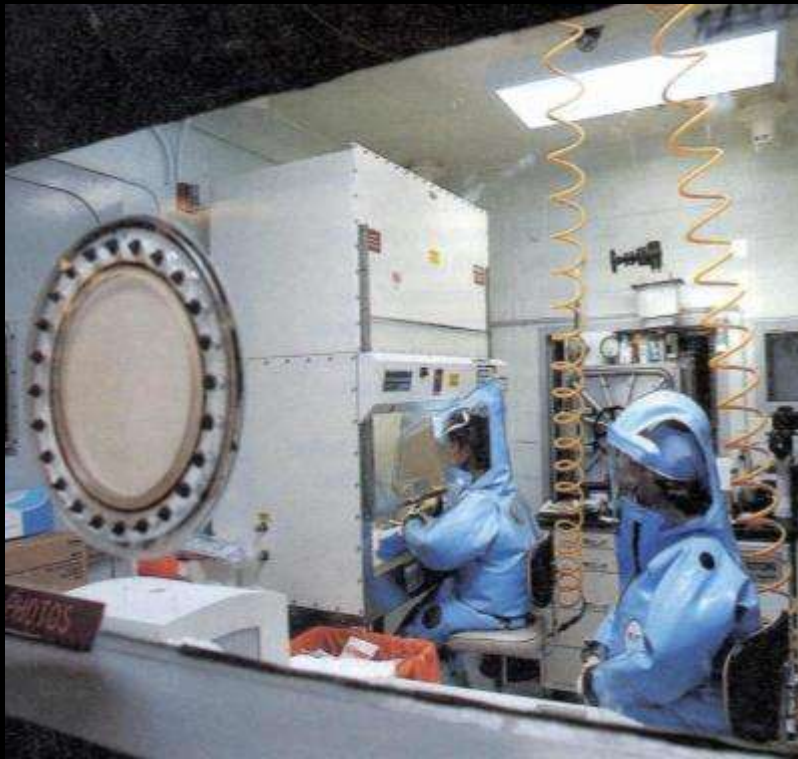
**The Single Most Important Leverage Point
For Rapid Mobilization of Resilient Responses
to Epi-/Pandemics, Epizootics and WMD Bioterrorism**

Genome Sequencing, Microbial Identification and Epidemiology

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



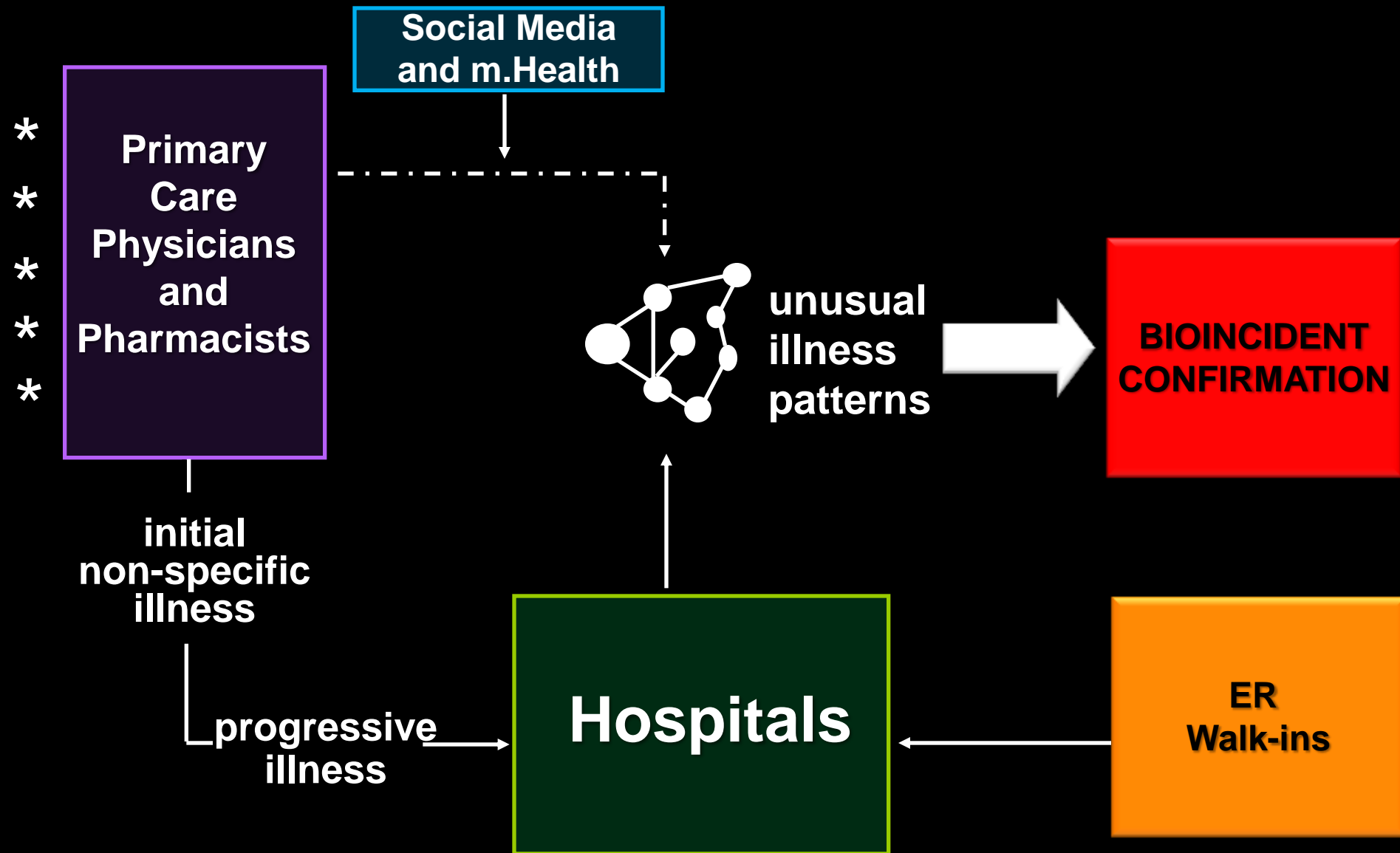
US States Poorly Prepared to Manage Infectious Disease Threats: Trust for America's Health and Robert Wood Johnson Foundation*



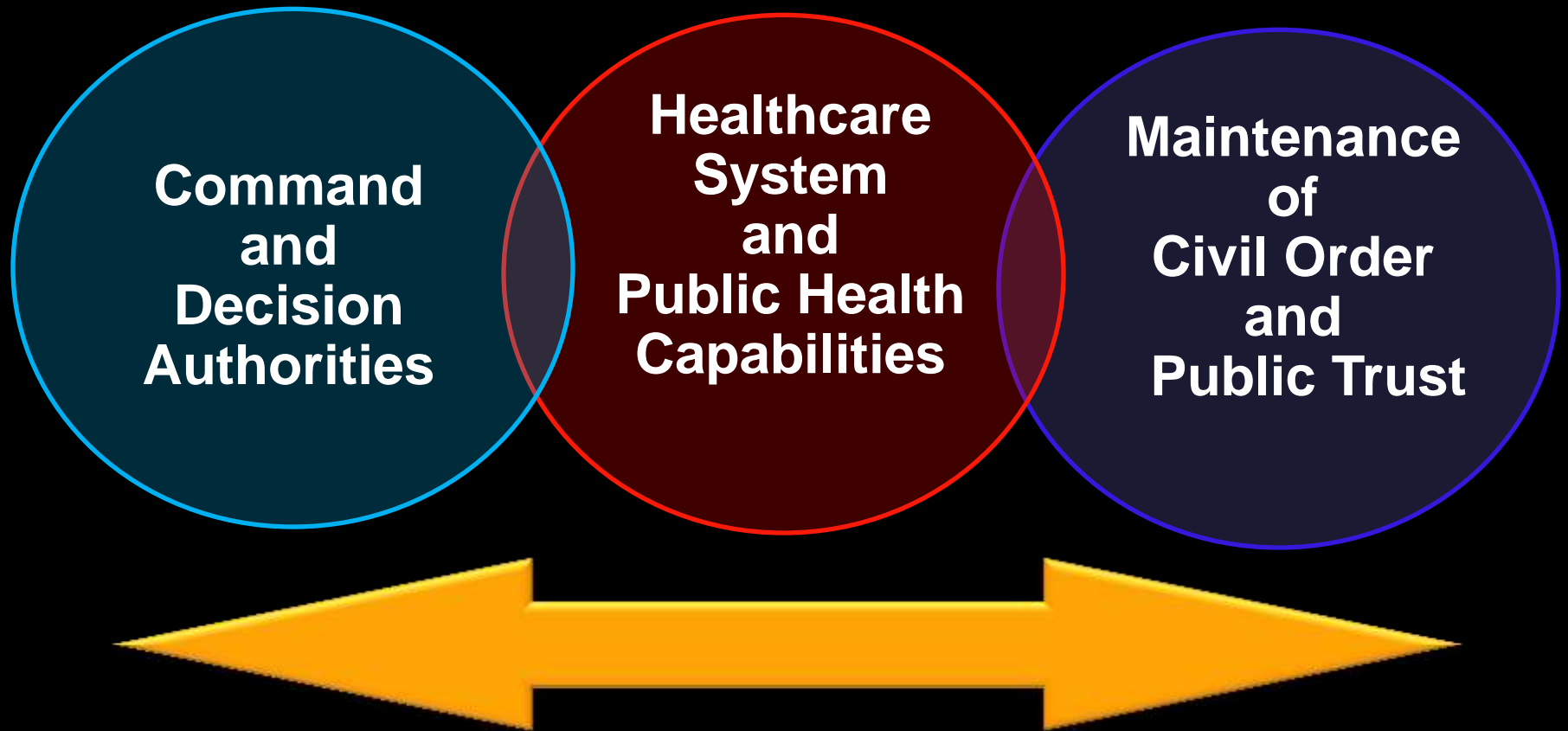
The Outbreaks 2013 Report
(<http://healthyamericans.org/assets/files/TFAH2013OutbreaksRpt14.pdf>)

- 33 states scored 5 or lower on scale of 10
- failure to ID select agent pathogens
- lack of common data reporting formats and/or obligations
- one-third do not have mandatory reporting of HAI
- failure to meet vaccination herd immunity levels (>90%)
- impact of fiscal austerity (State, Federal)
- 40,000 jobs lost in last 5 years

The Lag Phase in Bioincident Detection



The Three Core Components of Bioincident Management

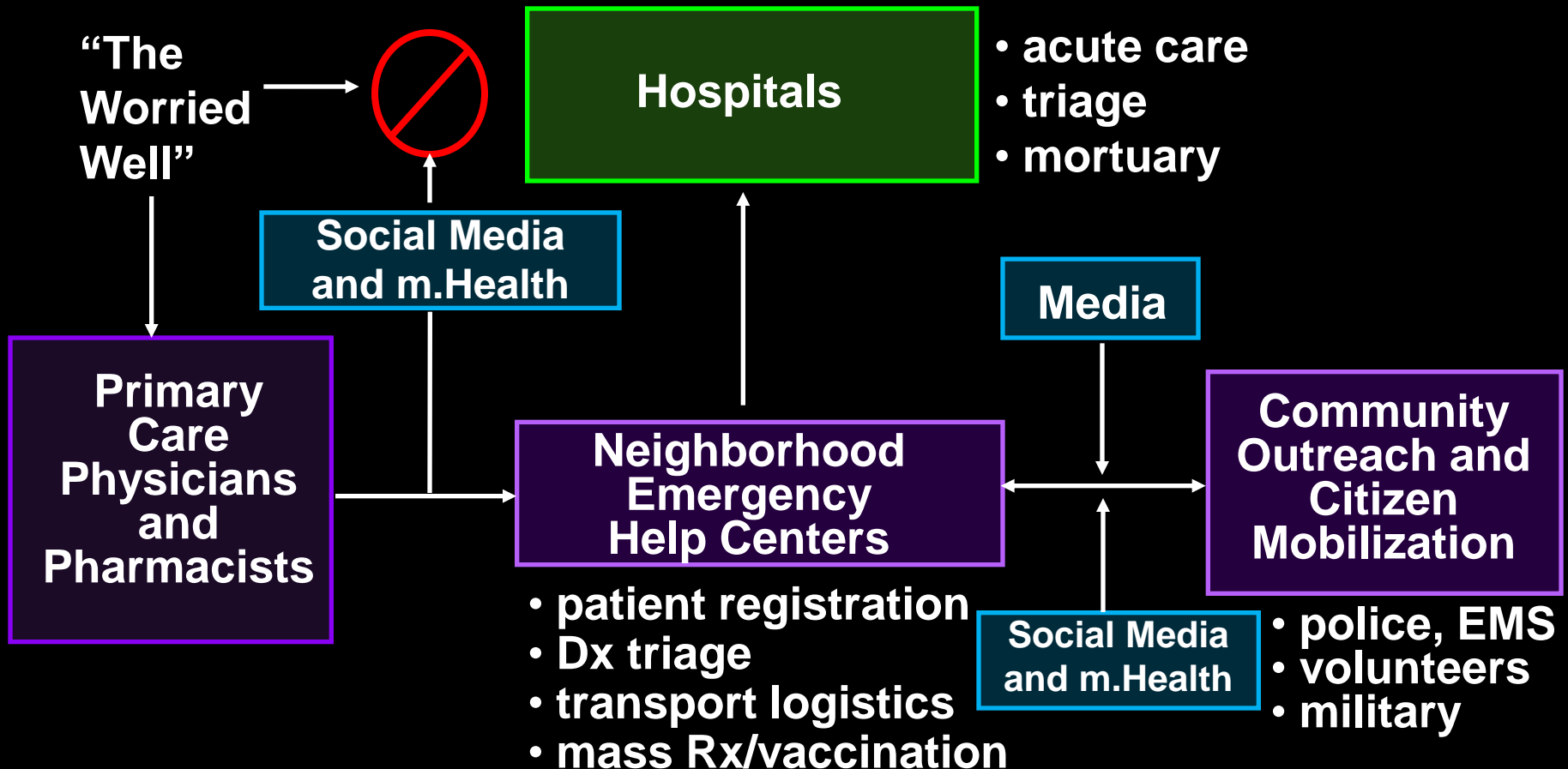


- robust inter-operable communication networks for real-time situational awareness and rapid actions
- managing the media and the 'worried well'
- transparency, credibility and public trust

Consequence and Crisis Control in a Bioincident: Compartmentalization and Calming

COMMAND CENTER

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



Consequence Management of a Major Bioincident

Logistics

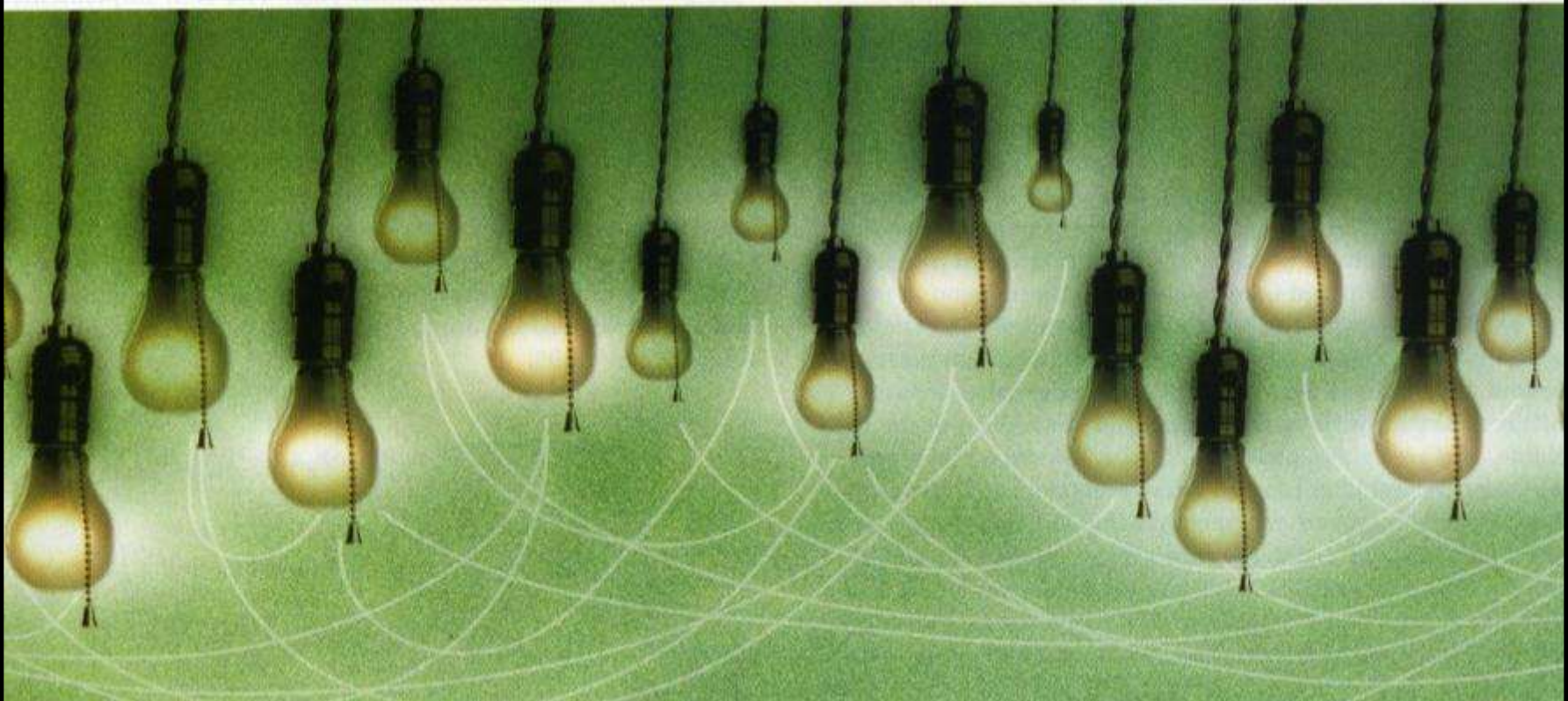
- **modular emergency services**
 - **expansion options and 'surge' resources**
- **non-healthcare sites for massive casualty management**
- **isolation and quarantine locations**
- **housing and welfare of staff (+ families)**
- **transfer of hospitalized patients to intermediate care facilities**
- **sites for distribution of medicines, food, water to public**
- **control of transport routes and supply chain logistics**

Preparedness: Building Resilient Systems

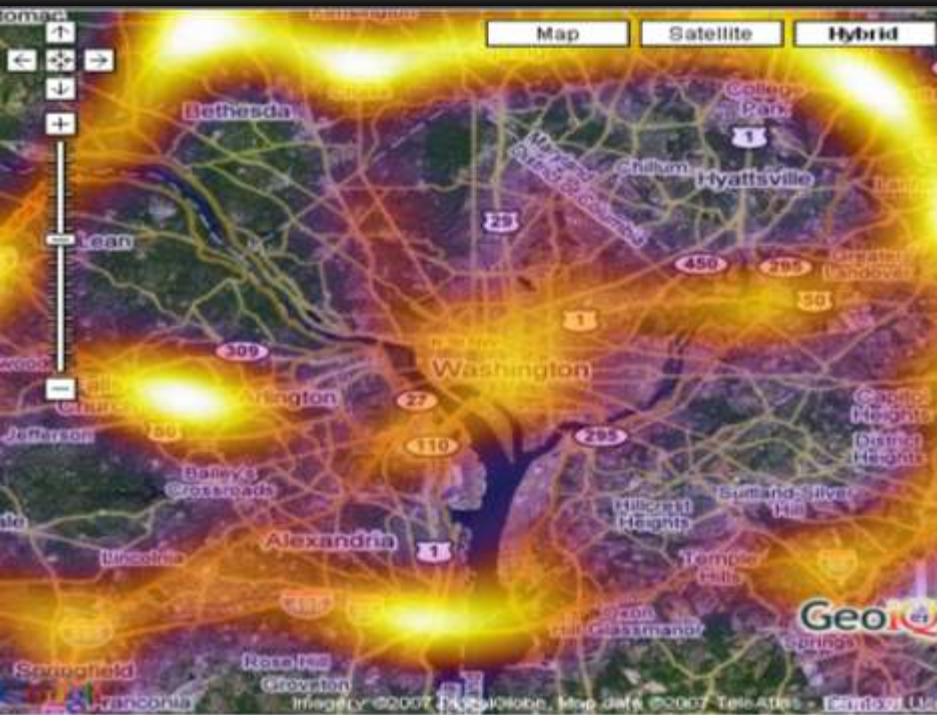
- are the necessary resources available: financial, personnel, skills, infrastructure?
- have all elements been tested under simulated emergency situations?
- are organizational structures and processes sufficiently agile for rapid response?
- are roles, responsibilities and accountabilities defined and understood for every constituency involved?
 - from local to global

Seamless Communication Networks: A Key Success Factor in Bioincident Management

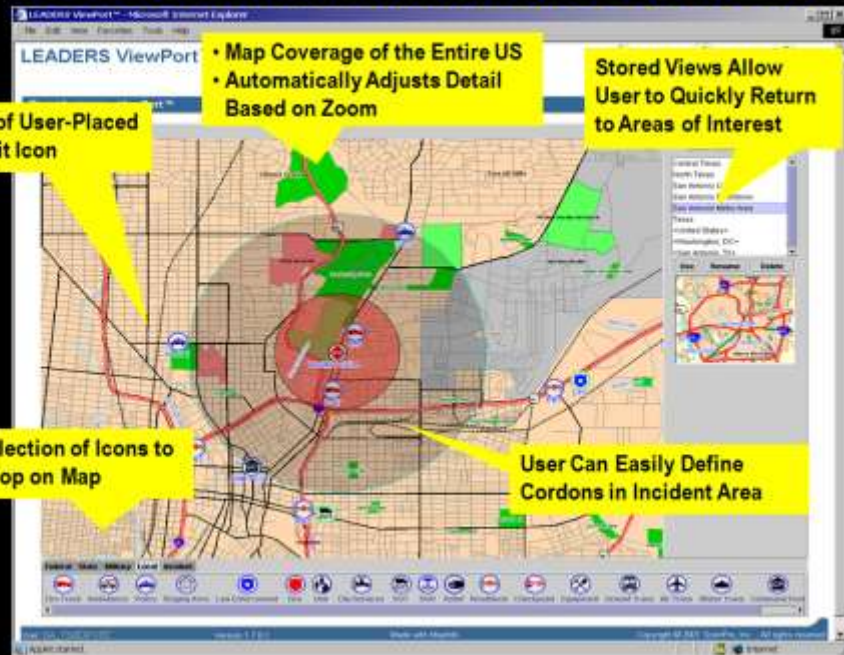
HELL IS THE PLACE WHERE NOTHING CONNECTS — T.S. ELIOT



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



Resource/Situation Awareness - ViewPort™



Distribution of Medical Emergency Supplies for a Major Epidemic/Pandemic



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

Potential Disruption of Access to Conventional Rx in a Major Epidemic/Pandemic



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

Medicines

- **“just-in-time” supply networks**
 - **major hospitals 2 or 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

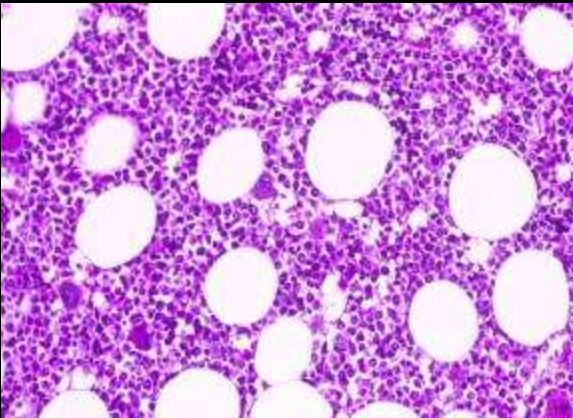
Children



Pregnant



Aged?



Immunosuppressed



**Impaired Major
Organ Function**



ICU-Critical Care

The Likely Real Picture!

“FOG”

“FUBAR”

Ill-Defined Responsibilities and Accountabilities

**Lack of Well-Rehearsed Master Plans:
Federal, State and Local**

Public Ignorance, Fear and Media Sensationalism: A Potent Triad

**The first question President Obama received during his press conference on April 29, 2009 was:
“Why aren’t you closing the Mexico-US border to prevent the entry of swine flu (SO-H1N1)?”**



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 any major level of fatalities will be unprecedented in modern peace times with unpredictable consequences for public responses**
- **unpredictable unilateral decisions by other governments, restricting trade, travel and shipment of goods**
- **extended supply chains might break down completely**

The 'Fog of Disaster': Crisis Standards of Care and Proliferation of Unanticipated Events and Consequences



LIFE AND DEATH IN A STORM-RAVAGED HOSPITAL

FIVE DAYS AT MEMORIAL

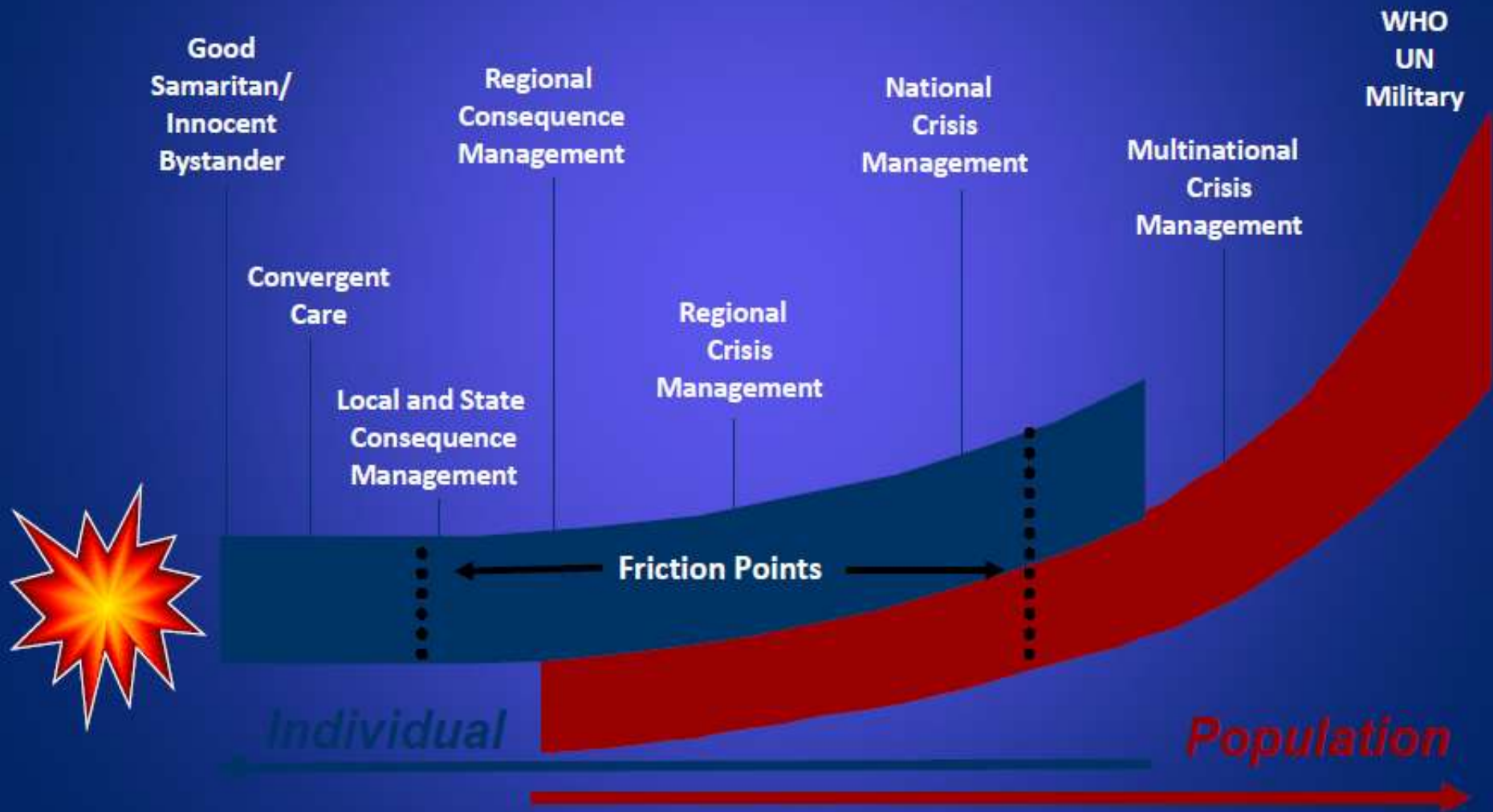
FIVE DAYS AT MEMORIAL

SHERI FINK

SHERI FINK



Mass Casualty Care: Transition from Individuals to Populations

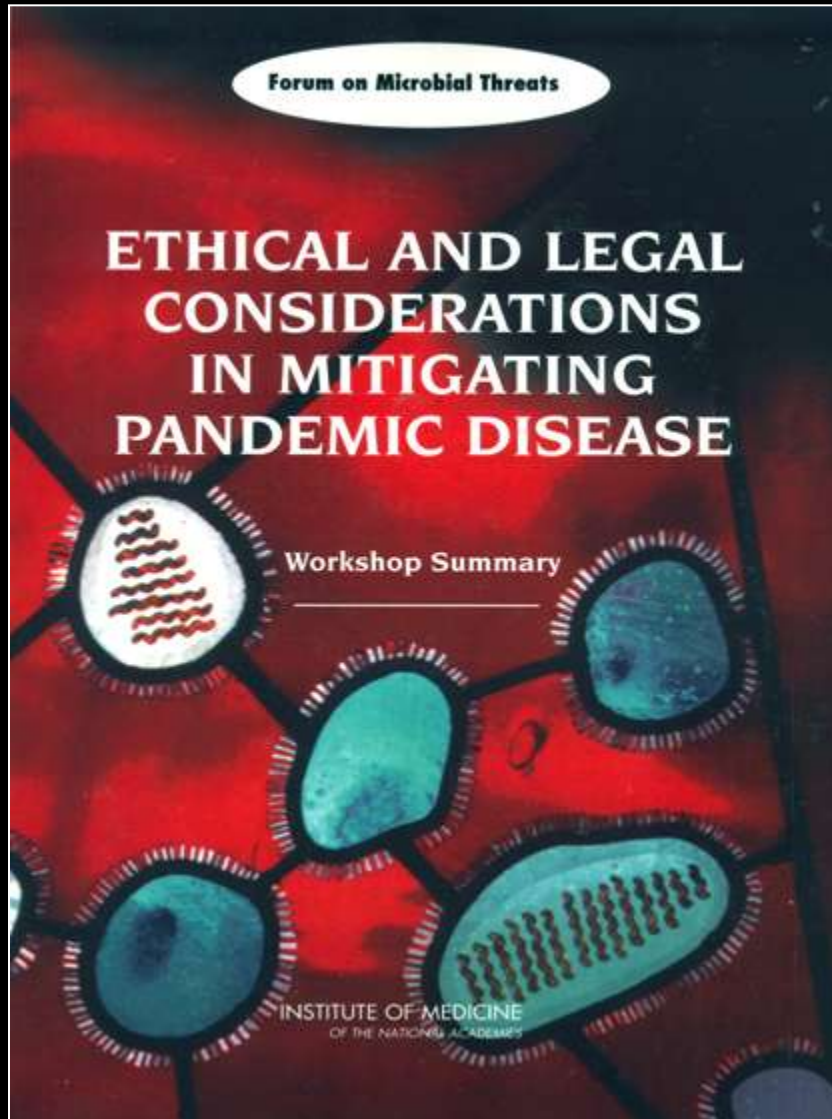


The Fragmented Silos of USG: A Dangerous Vulnerability





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

Changing Clinical in a Bioincident: From Standard of Care to Sufficient Care

- **provide the most good for greatest number of people under adverse conditions and constrained resources**
- **clinical triage**
- **rationing of health resources/pharmaceutical**
- **omnipresent vulnerabilities and risks from public panic and civil disorder**

Who's In Charge?

“I’m In Charge”



“DHS will manage and direct the Federal Response to a pandemic of avian flu.”

Secretary Chertoff 23 August 2005



- **DHHS and many in the public health community objected to this declaration**
- **asserted that DHS was “incapable of understanding the complexity of a medical disaster”**
- **DHHS subsequently directed to be lead agency**

DOES DHHS OR THE PUBLIC HEALTH AND CLINICAL COMMUNITIES REALLY “UNDERSTAND THE COMPLEXITY OF A LARGE SCALE DISASTER?”

Who Is In Charge?

- **delusional to believe that optimum disaster response is a physician/health system-centric process**
- **crucial medical component but multi-disciplinary, multi-sector 'bigger picture' complexities require sophisticated integration and operational expertise in large scale logistics and disaster exercises**

Failure of Power Generators in Major NYC Hospitals During Superstorm Sandy 1 November 2012



Cascading Effects:

**The Consequence of Inter-Connectivities
In Complex Systems**

Control of Population Movement and Supply Chain Networks



Compromising Critical Systems

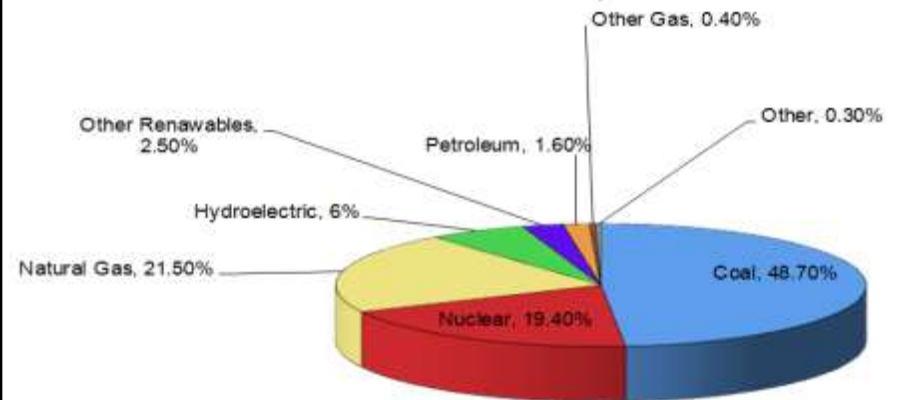


Vulnerability of Global, National and Local Supply Chains in a Major Epidemic/Pandemic

Energy



Net Power Generation in the US by Fuel Source, 2007



Medical Consequence Management of Major Bioincidents

Key Success Factors

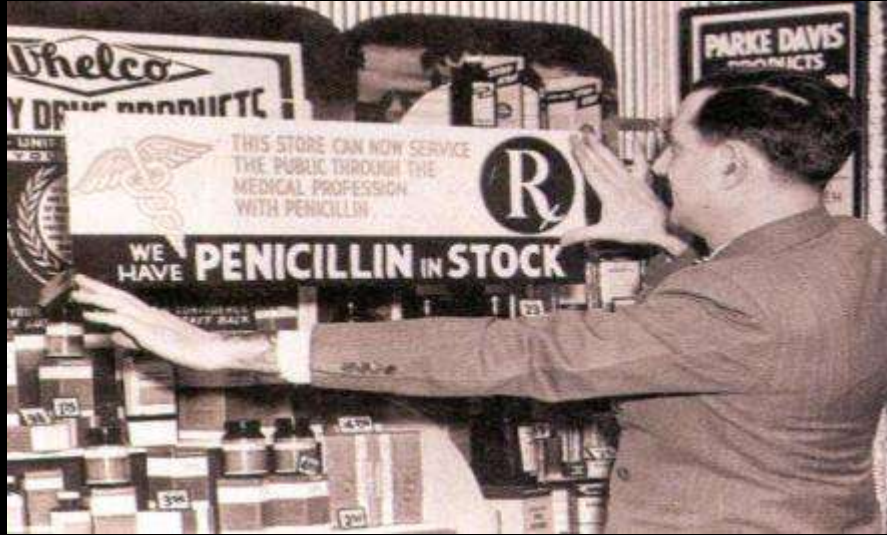
- **tested disaster management plan**
- **responder training and education**
- **command structure**
 - **demarcated roles, responsibilities, authority**
 - **robust communication channels**
- **single source POC for key interfaces**
 - **ground zero staff (multiple ground zeros in CBW)**
 - **emergency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

The Growing Threat from Infectious Agents

Asleep at the Switch!

Bad Bugs and Few New Drugs

Comfort and Complacency: The Enemies of Vigilance and Preparedness



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 baumannii

Pseudomonas aeruginosa

Enterobacter species



The Valley of Dea(r)th: 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**
 - **major gap in new agents for therapy of G-bacilli**
 - **lack of systemic agents in advanced development for organisms resistant to all current antibacterials**

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, Fierce Biotech (23 Oct. 2009)

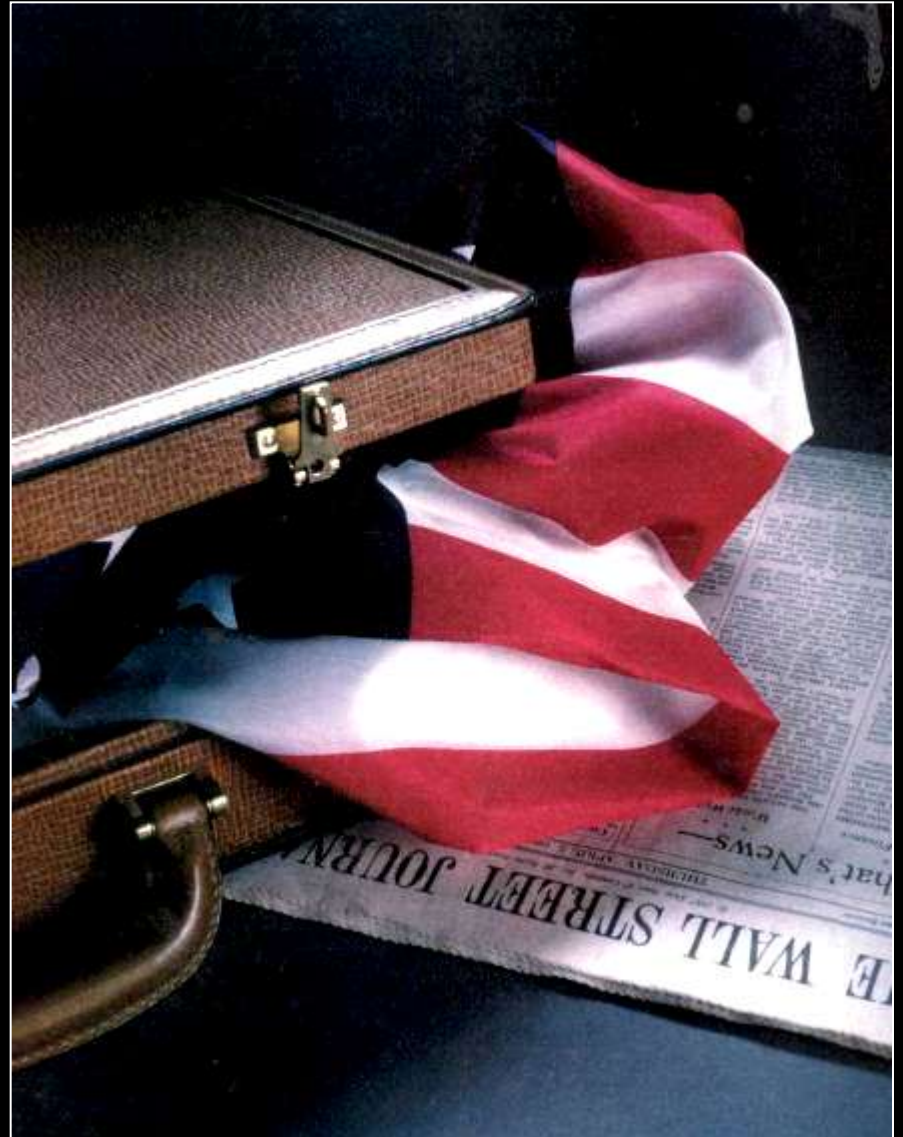
Vaccine Safety: Media Sensationalism and Celebrity Quackery



Who Pays for Preparedness?



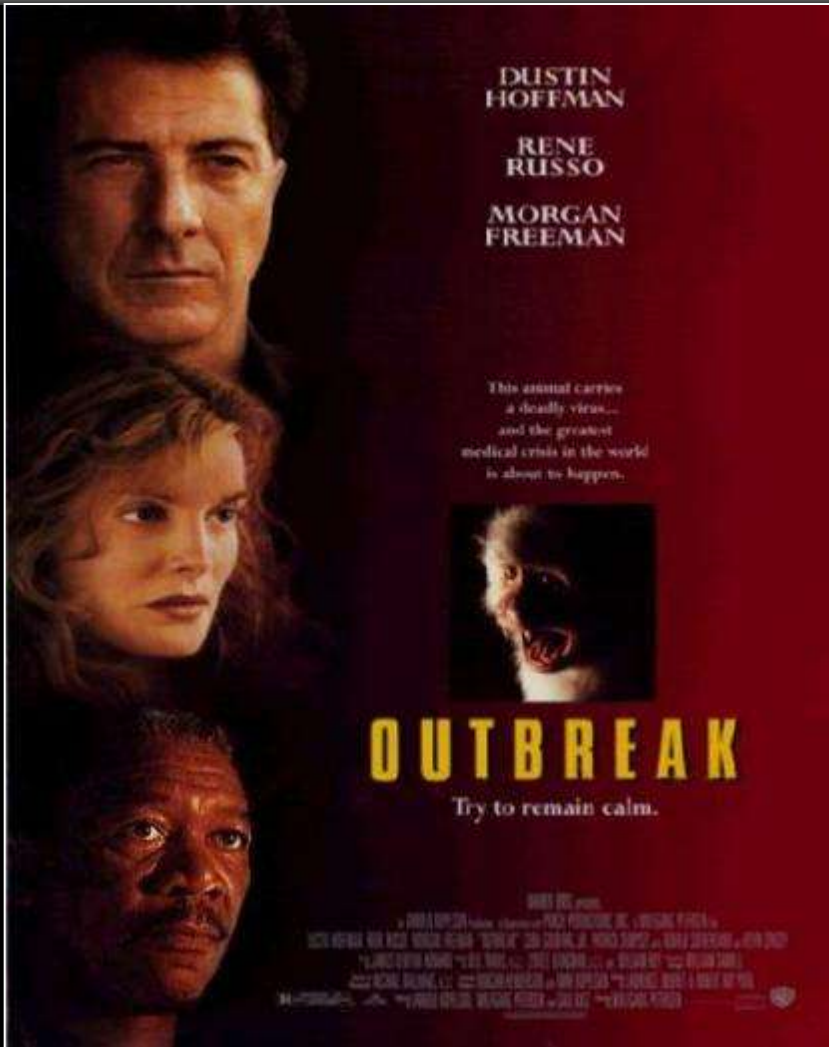
The Obligate Role of Private-Public Partnerships in Biosecurity Policy



Biosecurity

- **who pays for preparedness? (public policy, market dynamics)**
- **who is responsible/accountable for biosecurity? (public policy, organization, politics, media responses)**
- **what is the balance between public and private sector responsibilities?**
- **myriad ethical and legal issues (surveillance, civil liberties, rationing, counter-terrorism targets, publication of dual-use knowledge)**

Hollywood Doesn't Live in the Real World (Really?)



..... 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 Modern Industry

- **\$750 million to \$2 billion R&D cost/drug**
- **9-15 year R&D cycle**

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

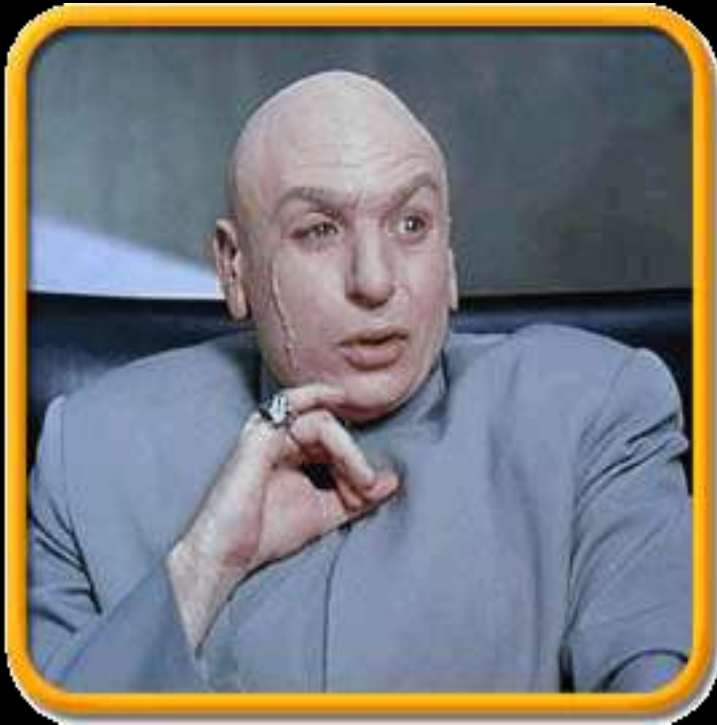
Chris Hentshel

Medicines for Malaria Venture: Lancet (2004) 363, 2198

New Incentives for Industry R&D Investment in Novel Anti-Infectives and Vaccines

- **‘orphan-drug’-type incentives for ‘prioritized’ diseases**
- **R&D tax credit**
- **extension of patent life or market exclusivity**
- **transferable priority review vouchers for expedited review of another product**
- **advanced purchase commitments**
- **‘non-use’ market compensation for next-generation agents held ‘in reserve’ to combat pan-resistant infections**

Future Trajectory Trends and Threat Expansion



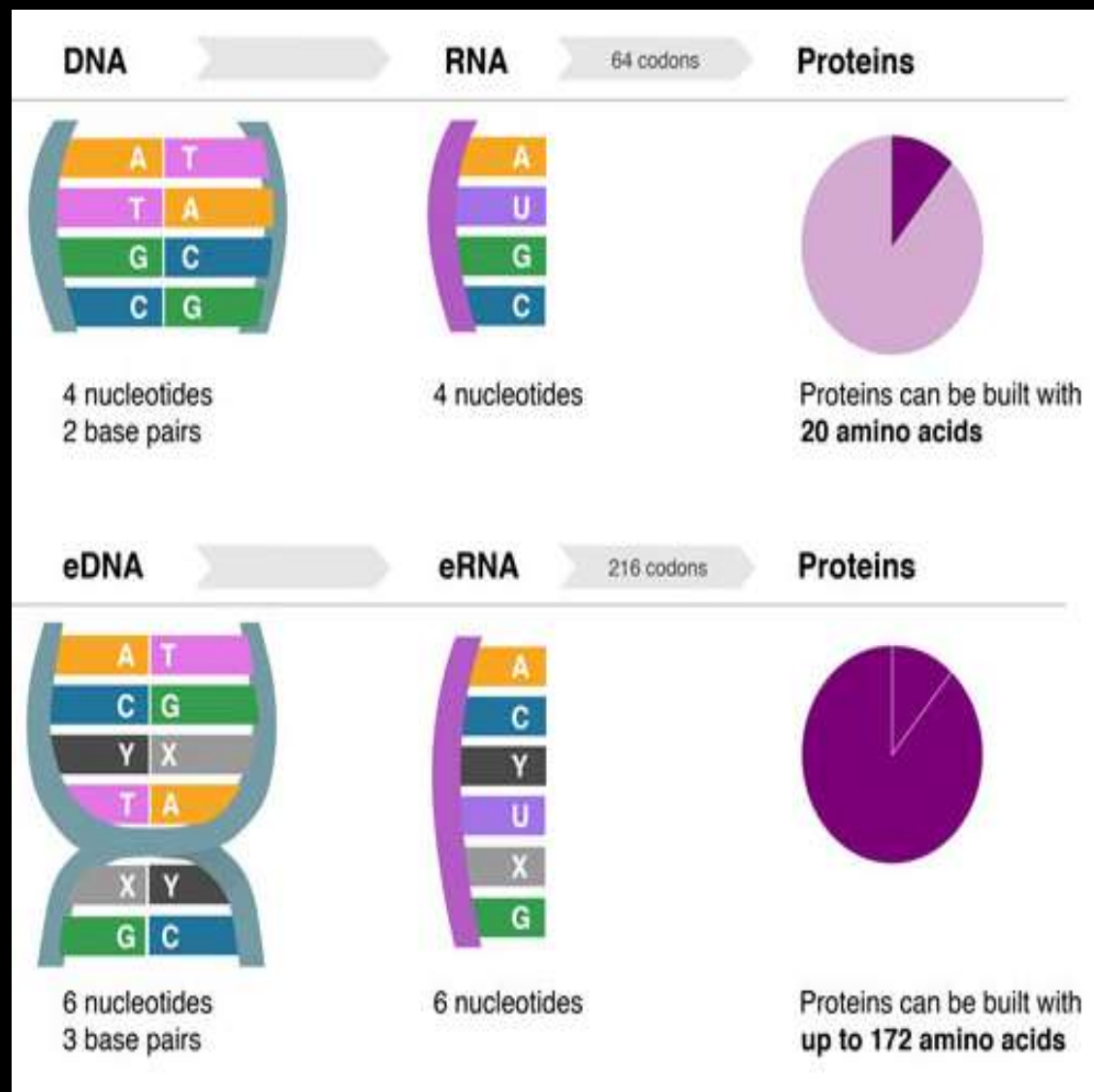
New 'Dual-Use' Technologies

Dual-Use Technologies

Expanding the Biothreat Spectrum

Synthetic Biology: A Powerful Dual-Use Technology

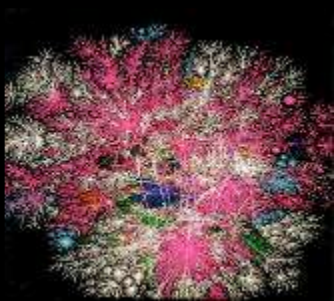
Synthetic Biology: New Dual-Use Dilemmas



The Expanded Dimension of the 'Bio' Challenge



- **thinking beyond 'bio' as just infectious agents**



- **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**

Dual-Use Research of Concern (DURC)

Nature (2012) 482, 153

COMMENT

INFLUENZA Further explanation of the NSABB recommendations p.158



PRIMATE Imitation and social learning in apes p.160

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

CANIS VULPINUS 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



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Dual-Use Research of Concern (DURC)



the WHITE HOUSE PRESIDENT BARACK OBAMA

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Proposed Policy Targets Dual Use Research of Concern

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Posted by Franca Jones on February 21, 2013 at 09:25 AM EST



Public Health Emergency

Science Safety Security
Finding the Balance Together

DEPARTMENT OF HEALTH & HUMAN SERVICES

Framework for Guiding Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets

Posted February 21, 2013

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

Biosecurity: A Growing Void in USG Policy, Planning and Preparedness

silos subvert solutions

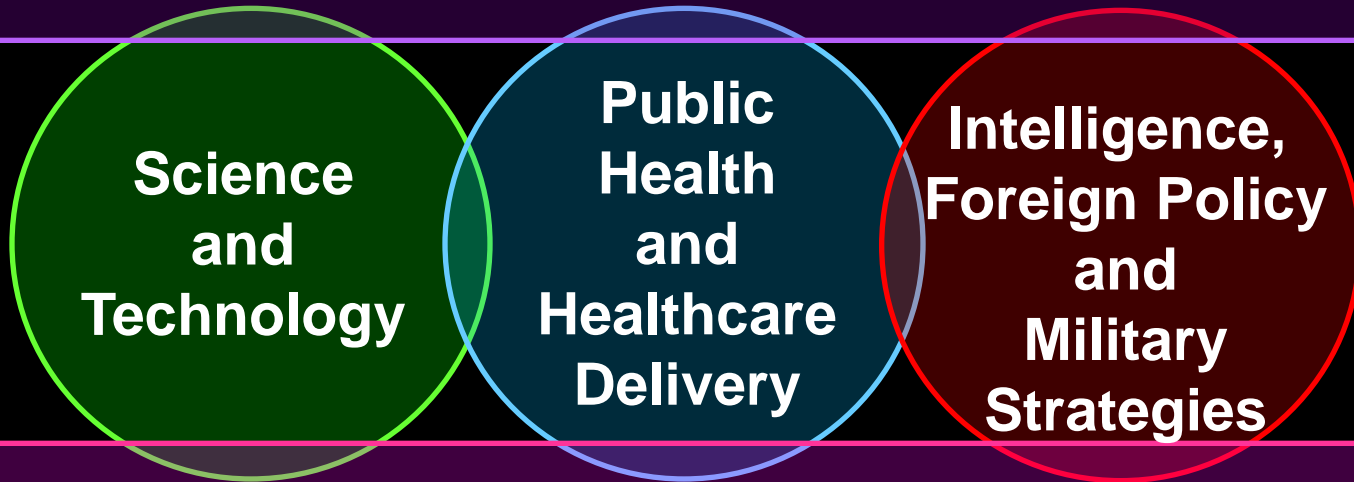
**multi-dimensional challenges demand cogent,
holistic solutions**

**current US capabilities are dangerously fragmented
and under-resourced**

**bugs don't respect borders:
biosecurity cannot be addressed solely from a
narrow national perspective**

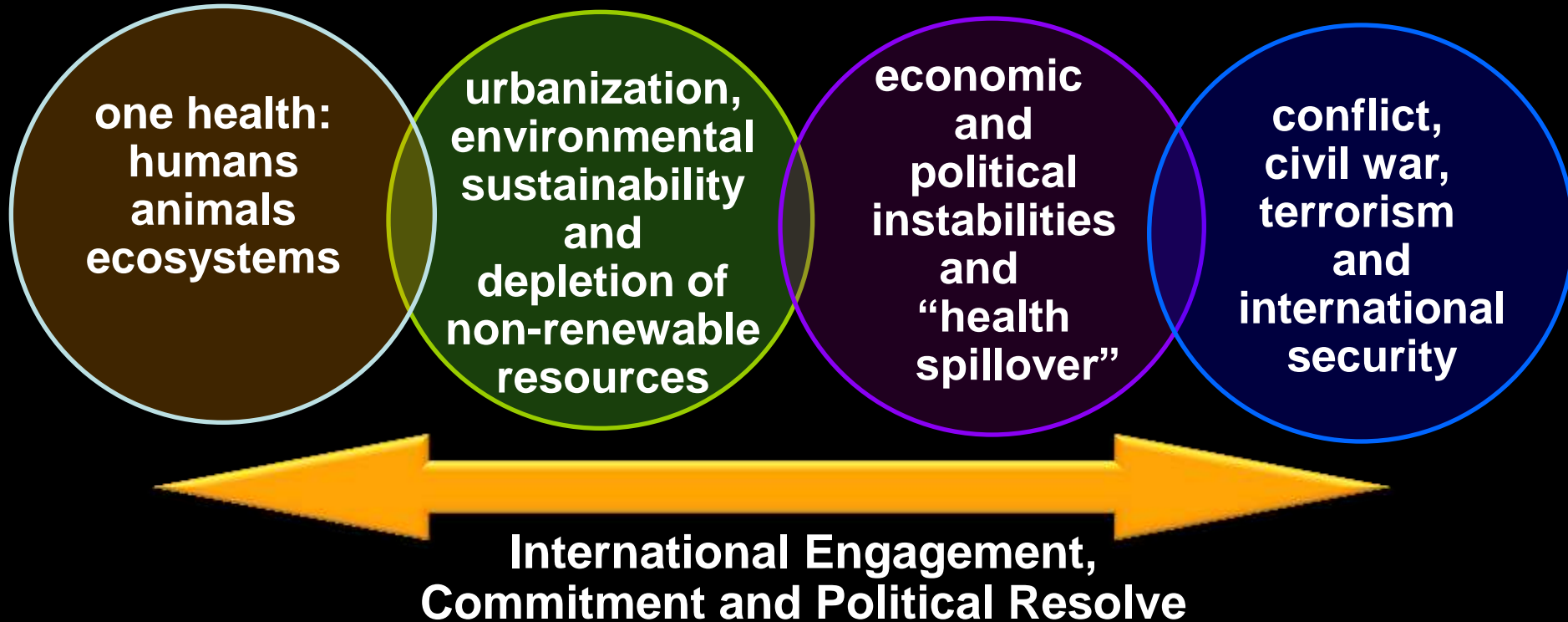
Biosecurity: A Classic Complex Systems Challenge

- global impact
- biological, social, economic, technical, political and military

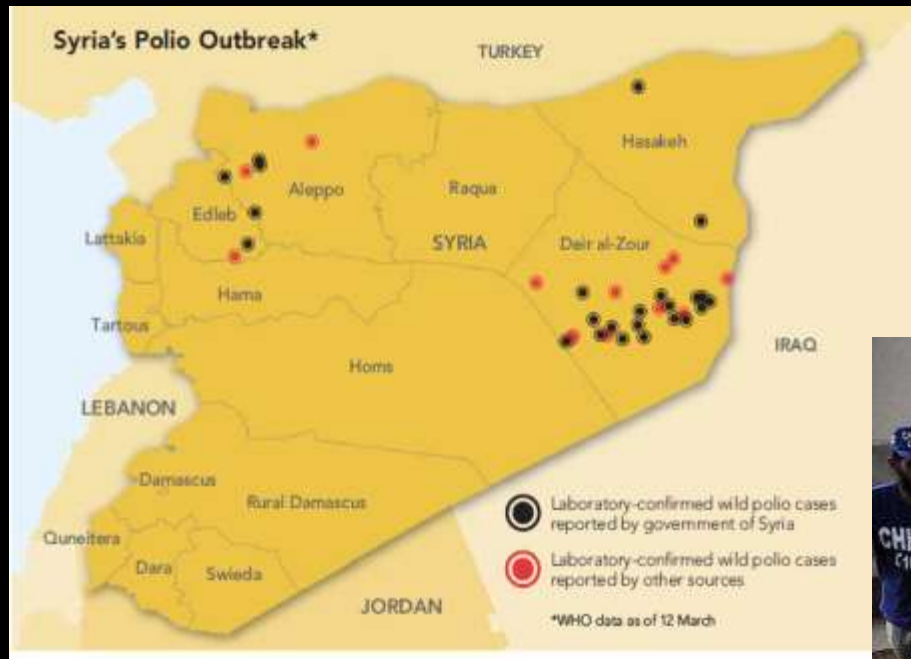


- societal priorities and cost of biosecurity
- political and military conflict: ideologies, intents and capabilities

The Multi-Dimensional Complexity of Biosecurity



Fighting Polio in Regions of Political Instability



Africa: A Zone of Escalating National Security Challenges With 'Spill Over' Health Effects



- **widespread proliferation of defense spend**
- **civil wars and instabilities**
- **jihadic fundamentalism:**
Al-Qaeda, Al-Shabaab, Abu
Lyad al-Tunisi, Boko Haram

Conclusions:

Biosecurity

**Understanding the Global Impact of Increasingly
Inter-connected Biological Systems**

**Medicine, Agriculture, Environmental Sustainability
and National Security**

Building Robust Defenses for Biosecurity

- **naturally occurring infectious diseases pose an equal, and likely greater, current threat to society than 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**

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 vaccines
- global political engagement and commitment



The VUCA World

- **V**olatility
- **U**ncertainty
- **C**omplexity
- **A**mbiguity

**WHAT TO EXPECT,
WHEN NO ONE'S EXPECTING**

The Need for Greater Urgency and Adoption of Systems-Based Approaches to Biosecurity

- **current USG institutions and academia are ill-suited to address current and projected R&D challenges**
- **‘rapid’ and ‘translation’ are countercultural to much of the academic and USG communities**
- **the cosmetic salve of seeming to ‘do something’ is meaningless absent of results**
- **extravagant resources are/will be wasted until a forceful integrated, ‘systemic’ approach is adopted**
- **the engagement of corporate and international agencies is a critical success factor in addressing global biosecurity challenges**

Building Robust CB Defenses

- **major vulnerabilities exist across the full spectrum of biosecurity**
 - **pre-emptive detection and interdiction**
 - **rapid diagnosis**
 - **healthcare resources for mass casualty management**
 - **drug and vaccine coverage (quantitative and qualitative)**
 - **outdated public health laws**
 - **emergency control of media/commerce**



The Curse of Contemporary Governance: 'Quick Fixes' and the Retreat from Complexity

- **society increasingly “cocooned” from complexity and risk**
- **pervasive and dangerous scientific illiteracy among legislative and policy makers about biosecurity**
- **“quick fixes”: uni-dimensional, short term policies that do not address long term, multidimensional complexity**
- **public policy defined increasingly by length of legislative terms**
- **influence of media in shaping public policy and operational constraints**

Ignoring Systems Complexity: Void in Global Public Health and National Security

- **pernicious constraints on USG analysis and decision-making frameworks**
- **growing expertise gap in USG agencies**
 - **threat diversification, new technologies**
 - **open-source analysis**
- **under-leveraged engagement with private sector**
 - **novel technology trajectories**
 - **broadening international scope**
 - **expertise pool**

**MUST CATASTROPHE BE THE ONLY VEHICLE
TO PROVOKE RADICAL REFORM?**



**“History is the sum total
of the things that could have been avoided.”**

Chancellor Konrad Adenauer

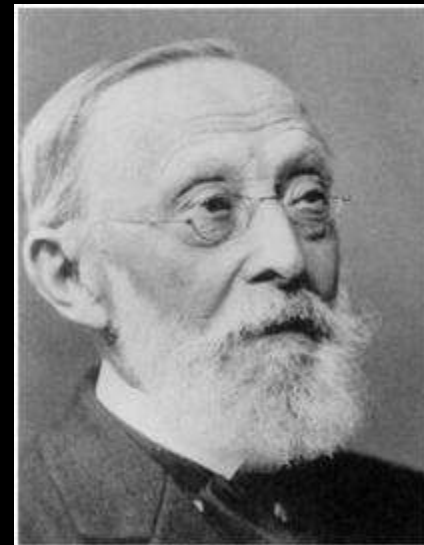
**“Politics is the art of the possible,
the calculated science of survival”**

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/>

