

**MEETING OF THE STATES PARTIES TO THE
CONVENTION ON THE PROHIBITION OF
THE DEVELOPMENT, PRODUCTION AND
STOCKPILING OF BACTERIOLOGICAL
(BIOLOGICAL) AND TOXIN WEAPONS AND
ON THEIR DESTRUCTION**

6 August 2004

ENGLISH ONLY

Second Meeting
Geneva, 6-10 December 2004

Meeting of Experts
Geneva, 19-30 July 2004
Items 5 and 6 of the Agenda

Presentations Submitted by the United States

Note by the Secretariat

1. In the course of the Meeting of Experts, the delegation of the United States of America made a total of 17 presentations. The text of 16 of these presentations has been extracted from the slides and submitted to the Secretariat for reproduction and inclusion on the Official Document System (ODS).
2. The 16 presentations are annexed to the present note and reproduced in the language and format in which they were received, without formal editing.

Annex

1. Cost Effective Animal Disease Surveillance

Redefining Roles of USDA

- Historically, the charge of USDA has been:
 - Eradication of animal pathogens that impact human health or are economically important to trade or production
 - Prevention of foreign animal disease introduction into the US
- Disease eradication programs have been successful
- Increased risk of foreign animal diseases with global travel and increase in world trade
- Emerging diseases increasingly important
- Advent of agroterrorism issues
- Importance of a comprehensive surveillance strategy with emphasis on early detection

Governing agencies

- Animal disease surveillance in the U.S. is state based. OIE List A diseases require immediate reporting.
- USDA Animal Plant Health Inspection Services-Veterinary Services and the Centers of Epidemiology and Animal Health (CEAH) are the most prominent federal oversight agencies
- No single federal agency is responsible for all animal diseases

Disease Surveillance at USDA Slaughter Facilities

Food Safety Inspection Service Veterinary Medical Officer must be present for slaughter to occur:

- Every animal is examined antemortem for clinical signs of disease
- Every carcass is examined for evidence of gross pathology
- Collection of blood, tissues or other specimens
- Example disease agents
 - Brucellosis (serology)
 - Tuberculosis (pathology)
 - BSE (pathology)
 - Bluetongue (serology)
- Can also be used for emerging disease surveillance
- Veterinary medical officers are trained in recognition of foreign animal diseases

Animal Disease Surveillance through the Diagnostic Laboratories

- Laboratory credentials
 - 32 accredited full service reference laboratories (usually State Department of Agriculture)
 - Hundreds of local (often private) smaller labs
- Laboratory capacity- broad range of etiologic agents
- Sample Submission

- Voluntary- as part of a case workup
- Mandatory (for sales or interstate shipping)

Disease Surveillance on the Farm

- Distribution of livestock and poultry populations is a challenge
 - Cooperative Extension Service
 - Industry Partners
 - Private veterinarians
 - State veterinary medical officer
 - State Public Health Veterinarian
 - Educated Farmers
 - Use of sentinel animals
- Screening of animals prior to import and at import stations
- Flexible and responsive set of import regulations (changes based on global animal health intelligence)
- Syndromic Surveillance
 - monitoring of the frequency of illnesses with a specified set of clinical features in a given population without regard to a specific diagnosis
 - EVE (Emerging veterinary event data base) reports of unusual events related to animal health
 - ADAM is the mapping and analysis module that accompanies eVe
- Pathfinder
 - Web and newservice searching software that captures, stores and allows for analysis of data on animal health events occurring worldwide

Characteristics of Effective Surveillance

- Comprehensive (West Nile, Monkeypox)
- Coordinated
 - Surveillance activities should be coordinated from a single site embedded in an organization with adequate infrastructure and relationships. (Public Health Service, Wildlife Diseases)
- Integrated
 - Surveillance reports and databases should be broadly accessible and provide for seamless exchange of information
 - The surveillance process serves to connect the various segments responsible for addressing industry health concerns

Surveillance in Resource Limited Countries

- Surveillance is often seen as a costly operation with enormous personnel requirements
- Judicious deployment of resources can often achieve adequate surveillance without great expense

Disease Prioritization

Evaluation criteria:

- Impact on productivity
- Importance in animal or product export
- Feasibility of control
- Cost of control/surveillance
- Public health implications

Identification of critical surveillance areas

- Areas under direct threat of disease
- Border crossings
- Watering points or slaughter slabs near migration routes
- Auction pens and other major livestock assembly points
- Abattoirs and lairages

Surveillance in Non-critical Areas

- Less frequent visits by field personnel
- Annual “rapid appraisals” using group interviews
- Farmer awareness
- Information from other existing networks (crop extension, consultants, etc)

Surveillance Frequency

- Determined by the perceived risk of each point
- Determined by frequency of population turnover (along trade routes)
- Incubation period of the main diseases of concern
- Financial constraints

Farmer Awareness

- Train local livestock owners in disease recognition
- Encourage owners to report the presence of any suspicious clinical signs
- Incentives for evidence leading to the discovery of a disease
- Cost effective means for improving the quality of disease surveillance

Data from Private Veterinarians

- Legal requirements to report certain diseases to authorities
- Questionnaires
- Submitting of questionnaires required when submitting samples to the laboratory

Maintaining Laboratory Norms

- Laboratory testing needs standardization so that results of tests by different labs are comparable.
- Laboratories need to belong to networks where the same reagents and methods are used, experience and expertise are shared, and use is made of reference laboratories
- A chain of OIE and FAO reference laboratories has been established; it is important that national veterinary laboratories make use of these services.

Summary

- Ultimately, the exact type of surveillance adopted by a country is its own decision, based on disease risk and available resources.
- What is important is the issue of transparency.
- Each country should make the mechanics of its surveillance system known to neighbors and trading partners.
- Such transparency builds confidence, facilitates mutual risk analysis, and will promote investment and trade in the future.

National Animal Health Laboratory Network (NAHLN)

2. Reducing the Bioterrorist Threat in the 21st Century: International Dimensions

Bioterrorism is a real threat

“Armed with a single vial of a biological agent. . .small groups of fanatics, or failing states, could gain the power to . . .threaten world peace. America, and the entire civilized world, will face this threat for decades to come. We must confront the danger with open eyes, and unbending purpose.”

President George W. Bush
February 11, 2004

Defending Against Biological Threats

- U.S. has pursued aggressively a broad range of programs and capabilities to confront biological weapons threat.
- Result is *Biodefense for the 21st Century*
- Presidential directive builds on past accomplishments
- Roles and responsibilities shared across government agencies.
- Integration of national and global security, public health, intelligence, diplomatic and law enforcement communities.

Essential Pillars of U.S. Biodefense Strategy

- Prevention and Protection
 - Demonstrating political and financial support for nonproliferation and threat reduction programs translates into proactive prevention
 - Assessing vulnerability of and protecting critical infrastructure protection
- Threat Awareness and Assessment
 - Improving our ability to collect, analyze, and disseminate information
 - Ensure an integrated and focused effort to anticipate and respond to emerging threats
 - Vulnerability Assessment
- Surveillance and Detection
 - Early warning, detection and reporting systems to rapidly recognize and characterize dispersal of biological agents
 - Enhancing deterrence by improving attribution capabilities and improving capabilities to perform forensic analysis
- Response and Recovery
 - Plans for mass casualty care and risk communication
 - Accelerated development of countermeasures
 - Strategies, guidelines and plans for decontamination of persons, equipment, and facilities

The Strategy at Work—National Level

- State and local public health and hospital preparedness
- Expanded National pharmaceutical stockpile
- Obtained smallpox vaccine for US population

- Biowatch: A network of biological sensors to improve surveillance in human health, food, agriculture and environment
- Enhanced protection against contamination of agricultural/food systems
- Enhanced research to speed development and acquisition of new medical countermeasures against biological weapons (e.g., Bioshield)

G-8 Bioterrorism Initiative

Commitment to concrete national and international steps to: “. . .expand or, where necessary, initiate new biosurveillance capabilities to detect bioterror attacks against humans, animals, and crops; improve our prevention and response capabilities; increase protection of the global food supply; and respond to, investigative, and mitigate the effects of alleged uses of biological weapons or suspicious outbreaks of disease.”

Prevention

- Australia Group
- Cooperative Threat Reduction
- Law Enforcement Cooperation/Interpol
- Enhanced Biosecurity Practices
- Global Partnership to Combat the Spread of WMD
- Ottawa Group
- Criminalization of WMD Proliferation
 - National legislation
 - UN Security Council Resolution 1540
- Proliferation Security Initiative

Surveillance & Detection

- World Health Organization
 - Program for the Preparedness of Deliberate Epidemics
 - Global Outbreak Alert & Response Network
- Global Health Security Action Group
- Partnerships with Bordering Nations
 - Interoperable biosurveillance systems along borders
- APEC Public Health Security Initiative
 - Regional Emerging Disease Identification Center
 - APEC Emerging Infections Network

Response & Recovery

- WHO Smallpox Vaccine Reserve
- NATO Virtual Stockpile of NBC Countermeasures
- Joint Preparedness Training & Exercises
- Mutual Aid Agreements

WMD Medical Countermeasures

- Prioritize federal initiatives
 - Address immediate and long-term needs
 - Recommend national requirements for vaccines, drugs, antitoxins, diagnostics
 - Represent needs of civilian and military
- Coordinate research, development, and acquisition efforts of key federal agencies: HHS, DHS, and DoD
- Accelerate development via public-private partnership

Department of Health and Human Services

(Centers for Disease Control and Prevention)

(Food and Drug Administration)

(National Institutes of Health)

Department of Homeland Security

Department of Defense

Department of Agriculture

Department of Commerce

Department of Energy

Department of Veterans Affairs

Environmental Protection Agency

National Space and Aeronautics Administration

Intelligence Community (FBI, CIA)

Homeland Security Council

National Security Council

Office of the Vice President

Office of Science and Technology Policy

Office of Management and Budget

Regional Centers of Excellence for Biodefense and Emerging Infectious Disease Research

- Animal rule creates dependence on animal models
- Need to develop and improve understanding of models and aspects of comparative pathology
- Build upon knowledge base of veterinary sciences and use translational research capacity to make next generation therapeutics, vaccines, diagnostics (e.g., FMD, influenza, SARS, etc)
- Collaborative research with local, state and federal agencies required

Future Opportunities to Contribute to Homeland Security

- Identify and prioritize needs and develop mechanisms to fill gaps
- Diverse and valuable skills need to be recognized in science, policy and public arenas
- Become familiar with existing resources, programs, and where most value can be added
- Define leadership and avoid competing agendas
- Enhance communication tools and facilitate information sharing and coordination
- Strengthen existing and build new partnerships wherever opportunity exists

3. Role of Information Sharing and Communication Technologies in Disease Surveillance

Preparedness and Response

<u>Phase</u>	<u>Examples of Actions</u>
Pre-incident planning	information exchange - connectivity “diagnostic capacity” surveillance
Detection and Alert	aberration detection/assessment alerting *
Incident Response	investigation response/intervention communication * coordination of response resource management
Maintenance	feedback/improvement of systems education/training* research/development

Connectivity and Alerting

- Information exchange: connectivity meeting Health Alert Network standards (high speed continuous internet access, ability to receive emergency broadcast health alert messages)
 - 50 states and Guam
 - 2,142 counties (68% of US counties)
 - 13 states have 100% of counties connected
 - 42 states have plans to include private providers; currently 2500 hospitals & 6000 physician offices
- Alerting:
 - 9/11 alert sent via HAN within 4 hours of WTC attack, advising on need for heightened surveillance
 - Since 9/11 hundreds of alerts, updates , and advisories sent

Diagnostic Capacity

- Laboratory Response Network (CDC & APHL) website for state public health labs and other labs
 - Protocols for BT agent testing, isolation, identification
 - BT reagent ordering
- Training for clinicians in presentation of diseases due to BT agents
 - State, HAN, & professional societies (e.g. IDSA) information dissemination to providers
 - CDC distance learning programs—e.g. Anthrax: what every clinician should know-- 796,000 viewers—satellite, internet, phone, VHS

**State, Local, Federal, International & Military
Laboratories Participating in the LRN**

Surveillance approaches for rapid detection of a bioterrorism event

- Informed alert health care provider notifies local or state health department 24/7 contact
- Routine public health surveillance system detects an aberration
 - National Electronic Disease Surveillance System (NEDSS) designed to move surveillance to web, accept data from electronic healthcare databases
- Healthcare databases and novel data sources (veterinary labs, retail supermarket sales, business absentee data, etc) analyzed or scanned with various aberration detection algorithms
 - Biosense provides sentinel data for all major cities
 - Systematic evaluation of utility needed

Communications for anthrax & smallpox vaccination 10/1/2001-1/02

- General public
 - 23 phone press briefings to 1,909 journalists, >12,000 mentions
 - 306 TV interviews: audience >370,000,000
 - 2 TV, 3 radio news packages rebroadcast 216 to 798 times
 - CDC Bioterrorism web page >12,000,000 downloaded info, >5,000,000 only visited

Communications

- Secure public health information, discussion
 - Epidemic Information Exchange (Epi-X) posted 95 reports since 9/11
 - provided secure discussion forum among state epidemiologists, local CDC investigative teams
- Health professionals
 - MMWR to >500,000 clinicians via e-mail & web
 - CDC's Distance Learning network hosted 10 programs with audiences of >1,300,000
 - 2,583 phone inquiries to Emergency Operations Center from health professionals

Event Communication “nerve centers”

Data management systems for HHS Secretary's Emergency Operations Center and CDC's Director's Emergency Operations Center

-- incident tracking, management of personnel and physical resources, statistical analysis and mapping, and surveillance and management of calls

Preparedness and Response

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Background information about PHIN process and components
What is PHIN?

- Gartner – a multi-organizational business and technical architecture
 - Technical standards
 - Data standards
 - Specifications to do work
- Is also a process
 - Commitment to the use of standards
 - Commitment to participating in development and implementation of specifications

Laboratory Response Network

- Goal – an integrated multilevel laboratory network to provide rapid and critical laboratory capacity
- Coverage of both biologic and chemical agents
- Participation of clinical, state and local public health, military, veterinary, agricultural, water and food testing laboratories
- Federal participants include FDA, NIH, FBI, DoD, DOE, USDA, EPA

Laboratory Response Network

Laboratory Response Network (LRN) provides

- Agent specific protocols
- Standardized reagents and controls
- Laboratory referral directory
- Secure communications and electronic laboratory reporting
- Training and technology transfer
- Proficiency testing
- Appropriate vaccinations for laboratory workers

Epi-X- The Epidemic Information Exchange

- A secure Web based system allows reporting of outbreaks, unusual cases, and other acute health events
- >1100 users from CDC, from all state health departments, the District of Columbia, Puerto Rico, the preventive sector of the military, and poison control centers participate
- 48 states have contributed reports
- 1000+ reports of outbreaks or requests for epidemiologic assistance have been posted.

National Electronic Disease Surveillance System

- NEDSS uses Public Health Information Network Standards for development of integrated, and interoperable web based surveillance systems at the state and local levels
- Includes tools for electronic messaging data transfer to health department from health care system:
 - Eg real time results from multi-jurisdictional clinical labs, which do 300,000 tests per day from all 50 states

PHIN – Select Progress

- First year of funding – 2004
- >4,700 PKI digital certificates installed nationally
- >55,000 HL7 standard public health lab results from 18 LRN labs
- >40 million patient records sent in HL7 format from DoD to public health (BioSense), > 30 million records sent in HL7 format from VA to public health (BioSense)
- >16,000 HL7 standard, clinical lab notifiable disease results sent to 15 states
- Reduction in communicable disease reporting time from ~30 days to 1-2 days (NEDSS Base System)
- Experience with making standards work in operating systems (benefits and issues)

Public Health Information Network – Process

- Document functional requirements to support public health activities (starting with preparedness)
- Identify relevant industry standards - technical and data
- Develop specifications based on the standards that are concrete enough to do work
- Fund through the functions, standards and specifications
- Make systems available to support these functions and that use these standards - now
- Develop software elements and artifacts to be used in other systems that implement the standards
- Support certification of the functions and specifications

Fund through the functions, standards and specifications

- Written into guidance as required for use of CDC and HRSA preparedness supplemental cooperative agreement funds
- CDC director has now stipulated that all CDC grants and cooperative agreements will have language about PHIN (and hence appropriate CHI and FHA) standards adherence

Make systems available to support these functions and that use these standards

- Systems may not meet all requirements, but implement standards that are available now
- Look to accelerate implementation – Application Service Provider (ASP) implementations, direct assistance
- BioSense, Outbreak Management System, PVS – Countermeasure
- Administration, Epi-X, HAN like alerting, NEDSS Base System

Develop software element that implement the standards to use in other systems

- Support standards-based compatible partner and commercial system development
- Modular software elements that can be used in systems to support different functions
 - PHIN Messaging System – bi-directional secure data exchange, “EDI,” via ebXML
 - PHIN Vocabulary Services – standard reference table and formal vocabulary support
- Other artifacts include logical data model, public health thesaurus, knowledge management metadata specification, etc.

Support certification of the functions and specifications

- Prototyped during Smallpox Vaccine Program – quickly developed a national infrastructure of state and CDC systems to support vaccine administration
- Three certification steps:
 - Identify requirements
 - Offer self-testing tools
 - Third party certification
- Two types of certification:
 - Functional capabilities of systems to meet needs
 - Discrete set of testable messages and metrics

4. Infectious Disease Surveillance

Background

- International organizations that currently operate infectious disease surveillance systems
 - World Health Organization (WHO) “network of networks”
 - Office of International Epizootics (OIE)
 - Food and Agricultural Organization (FAO)

Inhibitions to More Effective Disease Surveillance Systems

- Disease characteristics and national commitment affect surveillance quality
- Surveillance often constrained by shortage of human and material resources
- Multiple surveillance systems often poorly coordinated and not linked firmly to response measures

Inhibitions to More Effective Disease Surveillance Systems

- The influence of networks directed toward specific disease threats tends to weaken the surveillance capacity for other diseases
- Absence of clear response by responsible national authorities to disease outbreaks and lack of incentives for reporting often discourages participation in disease surveillance efforts

Organizations that Coordinate Global Disease Surveillance Systems

- World Health Organization: promote and protect programs whose objectives are the highest attainable degree of health
 - Resolution WHA55.16: Global Public Health Response
 - International Health Regulations
 - Global Outbreak Alert and Response Network

Animal Disease Surveillance

- Office International des Epizooties (World Organization for Animal Health): promote animal health and welfare and a contamination-free food supply
 - Transparency of animal disease status world-wide
 - International Animal Health Code
 - Member states report Category A and B diseases to OIE which then issues alerts and can provide technical assistance
 - Food safety activities

Food and Agricultural Surveillance

- Food and Agriculture Organization: improve global nutrition, rural development and agricultural productivity
 - *Codex Alimentarius*
 - International Plant Protection Convention
 - Emergency Prevention System for Transboundary Animal and Plant Pests and Diseases (EMPRES)

Importance of Surveillance

- Threat posed by new, emerging and reemerging infectious diseases and biological weapons
- Intra-national and inter-national borders are ineffective for containing diseases

- Need for current information about diseases in specific populations is increasing

Importance of Surveillance

- Surveillance provides information for action
- Can generate timely and accurate information on diseases, events and trends
- Basic responsibility lies with individual countries
- Legal underpinnings for cooperation are limited in scope, i.e., International Health Regulations do not provide a framework for addressing epidemics within countries

Strengthening BTWC by Improving Disease Surveillance

- Improved national and cooperative international disease surveillance is consistent with the object and purpose of the BTWC which is the elimination of biological weapons
- Participation in local, national or global disease surveillance systems represents one way of making progress on biological weapons nonproliferation through cooperation and transparency

Strengthening BTWC by Improving Disease Surveillance

- Surveillance at local and national levels provides primary defense against global spread of communicable diseases, and could alert international community to the possible use of disease as a weapon
- Global disease surveillance and control can only be improved by individual States Parties taking action and international cooperation

Improving Disease Surveillance

- Strengthening surveillance should not be automatically associated with increasing the number of health conditions included in the system
 - Impacts of adding additional health conditions for monitoring
- Systems must be sustainable both politically and technologically over time
 - Disease-based and syndromic disease reporting
 - Used regularly
 - Incentives and not penalties for reporting
 - International data sharing balanced against country sovereignty
 - Enjoy mandate of official authority

Improving Disease Surveillance

- Need to determine what improvements to surveillance systems are intended to accomplish
 - Early detection of outbreaks
 - Analyze trends
 - Generate hypotheses
 - Reduce global threat posed by biological weapons
- Need better integration of animal and plant diseases

Points to Consider

- Systemic improvements will be needed to improve surveillance of infectious diseases while maintaining progress against particular diseases of global concern such as HIV/AIDS, tuberculosis and malaria
- Improvement is incumbent upon each State Party through their active participation in local,

national and regional disease surveillance programs

- Improvement is also incumbent upon those international organizations responsible for operating global surveillance systems through better communication and coordination

Summary

- Strengthening general disease surveillance can improve responses and outcomes in cases of suspicious outbreaks of disease, emerging zoonoses or alleged misuse
- Improvements can best be accomplished through cooperation with the World Health Organization (WHO), Office of International Epizootics (OIE) and the Food and Agricultural Organization (FAO)
- States Parties are urged to support the WHO's efforts to strengthen the global system for disease surveillance, as well as to provide support to the OIE and FAO for improved surveillance of animal and plant diseases and food safety

5. Integrated Disease Surveillance: Human and Animal Health

1999-2004

The Public Awakens to Links Between Animal and Human Health Emerging and Re-emerging Zoonoses 1996–2004 (Source: WHO)

Zoonotic Diseases of Concern in the Americas

Integrated Surveillance Systems: Why the Concern?

- Early detection of disease in animal populations with timely communication between sectors important for prevention and control of disease in humans
- Little linking of veterinary to human data to date
- Multiple surveillance systems run by different agencies with little cross coordination
- Duplication of efforts, inefficient use of resources
- Not all zoonotic organisms are well addressed by surveillance systems nor are diagnostic tests available for wildlife
- No action plan for what will trigger a response

Selected Emerging Infectious Diseases Surveillance Systems in Humans, U.S.

- Emerging Infection Program Sites
 - Foodnet – 11 sites
 - Unexplained Death and Critical Illness Project; 4 sites
 - EMERGE ID NET- Infectious disease syndrome surveillance in 11 hospital emergency rooms
- IDSA Emergency Infections Network – internet-based system linking 500 infectious disease practitioners
- GeoSentinel – 22 linked travel medicine clinics in US and abroad to monitor disease among returning travelers

Surveillance of Disease Syndromes in Humans, U.S.

- “Drop in” – short term, for a defined event
 - World Trade Organization meetings
 - Presidential Inauguration
 - Republican National Convention
- More sustained - DoD Global Emerging Infections System – 7 syndromes in 313 military facilities
- BioSense
 - Lab response network, clinical lab orders, Prescription records, biowatch data, more-
- new data streams

The Missing Piece - Animals as Sentinel Surveillance for Emerging Zoonoses

- CDC - Purdue University Banfield Pet Hospital Syndromic Surveillance Project
- CDC - Cornell Zoo Surveillance System
- USDA - Food animals
- Live bird markets, exotic animal markets- to be developed

Other Novel Surveillance Systems for Zoonotic Disease: Use of NASA Satellites

Linking public health and veterinary diagnostic laboratories

Next Steps

New Partnerships

Summary

- 75% of emerging infectious diseases are zoonoses
- Humans have served as sentinels for emerging zoonotic infectious diseases; need to reverse the trend
- Recent global events reinforce the need for increased partnerships between human and animal health
- Surveillance for zoonotic disease in the US is not well coordinated
- Integration of human and animal surveillance requires multidisciplinary approach
- 2002 Public Health Security and Bioterrorism Act could be platform for integration of human and animal surveillance

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6. International Cooperation in Cases of Suspicious Outbreaks or Alleged Misuse

International Cooperation is Key to Global security

- Pathogens know no boundaries and international travelers and goods can spread a contagious disease quickly to persons in other nations.
- Increasing volume of international trade and migration requires that global surveillance networks be enhanced to meet the associated public health challenges.
- Early-warning surveillance, followed by prompt sharing of findings, plus a rapid and robust response, are public health and national security imperatives.

International Health Regulations

- WHO Member States working with WHO to finalize first major revision to WHO's International Health Regulations in over 30 years
- Target date for completion: 2005 WHA
- Emphasis on immediately reporting to WHO any potential public health emergency of international concern
- Strengthened abilities required for early warning surveillance, detection, response to infectious diseases

WHO's Global Outbreak Alert & Response Network

- "Network of Networks" complements and strengthens existing networks and builds on existing relationships and commitments.
- WHO and partners aim to improve the quality of international response, enhance the coordinated delivery of international assistance in support of local efforts, and make a significant positive difference to the lives of people affected by disease outbreaks.

Case of the Rajneeshee Religious Cult Oregon, 1984

- Bioterrorist attacks could be covert or announced and caused by virtually any pathogenic microorganism.
- Cult planned to infect residents with *Salmonella* on election day to influence the results of county elections.
- To practice for attack, they contaminated salad bars at 10 restaurants with *S. typhimurium* on several occasions before the election.
- Community-wide outbreak of 751 cases documented in county that typically reports fewer than 5 annual cases.

Case of the Rajneeshee Religious Cult Oregon, 1984

- Bioterrorism considered unlikely when the outbreak was being investigated by public health officials.
- Source of outbreak became known when FBI investigated the cult for other criminal violations.
- Vial of *Salmonella* identical to outbreak strain found in a clinical laboratory on the cult's compound.

- Members of cult subsequently admitted to contaminating salad bars and putting *Salmonella* into a city water supply tank.

Lessons Learned from West Nile Virus

- GAO/HEHS-00-180
- Links between public and animal health agencies are becoming more important.
- Assessment of laboratory capacity and improvement of linkages among laboratories are needed.

October 2001: First Bioterrorism-Related Cases of Anthrax in the United States

- *Bacillus anthracis* infections primarily occur through exposure to infected animals or contaminated animal products such as wool.
- After terrorist attacks on World Trade Center and Pentagon in 2001, envelopes containing *B. anthracis* spores mailed to news media companies and government officials.
- 22 cases, 5 deaths, possibly thousands of potential exposures.
- Attacks initiated response activities across the United States and in other countries and required considerable resources to support investigative efforts at local, state, and federal levels.
- Collaboration with law enforcement officials, clinicians, laboratorians, public health officials, and general public is essential.

Example of Global Outbreak Alert and Response: Rift Valley Fever

- Outbreak report received by WHO Alert and Response Network; WHO/affected country verify outbreak
 - Clinical specimens sent to reference laboratory
 - Data on suspect cases and geographical distribution analysed
 - FAO and OIE confidentially alerted
- If risk determined to be of urgent international importance, public health measures identified and recommended by electronic publication and publication in *Weekly Epidemiological Record*:
 - No measures recommended for products
 - Restriction of live animal exports recommended
 - Alert of travellers from affected area recommended on arrival in other countries with risk of RVF spread
 - Increased vector control recommended in neighbouring countries
 - Immunization of livestock recommended in risk areas
- Complete and coordinated outbreak investigation by affected country/±WHO and technical partners and containment of outbreak

Global Health Security Action Group

- Global Health Security Action Group (GHSAG) established by Health Ministers of eight nations and European Commissioner in November 2001.
- World Health Organization acts as important external resource.
- GHSAG aims to improve health security globally, and to better prepare for and respond to acts of biological, chemical, and radiological terrorism.

GHSAG Technical Working Groups

- GHSAG Laboratory Network
- Chemical Preparedness Workgroup
- Influenza Pandemic Planning Working Group
- Risk Management and Communication
 - Consolidation of risk management and smallpox technical working group activities

GHSAG Accomplishments

- Smallpox Preparedness Train-the-Trainers Workshop
- Smallpox Diagnostic Assay Validation Workshop
- Anthrax Diagnostic Assay Validation Workshop
- Global Mercury Command Post Exercise
- Report on strategies for isolation techniques
- Development of algorithms for assessment and management of potential threats
- Pandemic Influenza preparedness planning

Summary

- Challenges demand multidisciplinary approach.
- International cooperation is critical, in balance with need to address national security concerns.
- Enhanced public health infrastructure prepares us whether events are naturally occurring or intentional.

7. Disease Surveillance: U.S. Cooperation with Other Countries

A Global Approach to Disease Surveillance

- Global networks for disease surveillance and outbreak response
- Regional networks for disease surveillance and outbreak response
- National Networks for disease surveillance and outbreak response

Global and US Government Partners

- Multilateral
 - WHO/ HQ & Regional
 - OIE / FAO
 - TEPHINET
- Bilateral Relationships
 - Ministries of Health
 - Ministries of Agriculture

US Government

- Department of Health and Human Services (Centers for Disease Control & Prevention, National Institutes of Health, Food and Drug Administration, Office of the Secretary)
- U.S. Agency for Int'l Dev't
- Department of Defense
- U.S. Department of Agriculture
- Department of State

U.S. Department of Health and Human Services Cooperation

- High priority of HHS Secretary Thompson
- Supports multilateral surveillance efforts
- Field Epidemiology Training Programs
- Emerging Infectious Disease Programs
- Laboratory Response Network
- Disease research having surveillance components
- Early Warning Infectious Disease Surveillance
- US-Mexico Border Infectious Disease Surveillance (BIDS)
- Other

HHS / CDC Cooperation

- Field Epidemiology Training Programs (FETPs)
- HHS/CDC - Ministries of Health
- Builds capacity in epidemiology, surveillance, outbreak detection, investigation, response, disease prevention and control
- Training Programs in Epidemiology and Public Health Interventions Network--TEPHINET
- Essential link in global surveillance

International Outbreak Response HHS - National Institutes of Health

- Fogarty International Center Collaborative Networks
- NIAID supports research with surveillance components
 - Triatome Vectors and Chagas Disease

- Hepatitis E Virus infections in Bangladesh
- Drug-resistant malaria in Malawi
- Diarrheal disease in Brazil
- HIV/AIDS in Congo
- Remote sensing and GIS for schistosomiasis
- Influenza pandemic preparedness in Asia

HHS - Early Warning Infectious Disease System

- U.S. Mexico Border Health Commission- Cross-border early warning infectious disease surveillance
- Smart Borders: Canada – U.S. Bio-Security Collaboration
- U.S. Singapore Regional Emerging Disease Intervention (REDI) Center – regional approach- Asia
- Support WHO's GOARN, PAHO surveillance systems

U.S. Agency for International Development Cooperation

- With WHO: global strategy development; lab strengthening; detection of new pathogens; and development of technical guidelines
- Work in over 30 countries to build capacity in detection, analysis and response
- Supports regional surveillance in Africa and Latin America
- Research into behavioral barriers for use in data and cost analyses
- Development of guidelines for analysis of information and appropriate response
- Work with CDC and TEPHINET to strengthen epidemiology training capacity

Department of Defense Cooperation

- Global Emerging Infectious Disease Surveillance (GEIS)
- Supports global surveillance, training, research, and response to emerging infectious disease threats
- Respiratory, febrile, enteric illnesses, antimicrobial resistance
- Egypt, Peru, Thailand, Indonesia, Kenya, Navy, Air Force, WRAIR, AFIP
- 57 overseas laboratory partners
- Partners: GOARN, WHO regional offices, WHO collaborating centers, CDC IEIPs Bangkok and Nairobi

U.S. Dep't of Agriculture Cooperation

- Animal and Plant Information Service, International Services personnel, work with counterparts in foreign countries regarding animal disease status, surveillance, outbreaks

U.S. Support to WHO's Multilateral Surveillance Systems

- WHO Influenza Surveillance Network
- WHO Global Network for Polio Eradication & /Measles Elimination
- WHO Global Salmonella Surveillance
- WHO Global Alert and Response Network
- WHO Collaborating Centers
- Surveillance in support of global eradication of guinea worm disease
- Surveillance for vaccine-preventable diseases / EPI
- Molecular Typing - enteric pathogens (PulseNet); dangerous pathogens

- Anti-microbial resistance networks, e.g., TB
- GeoSentinel Disease Surveillance System
- AFRO Integrated Disease and Response

Summary

- Early detection of disease outbreaks is vital to minimize the magnitude and geographic scope of epidemics
- Multiple Departments and Agencies of the US Government are cooperating with other countries to support an effective global infectious disease surveillance and response capability

8. Investigations of Alleged BW Use or Suspicious Outbreaks of Disease

Investigations: Who, Where, What?

Investigations should be...

- Timely and Accurate
- Comprehensive and Objective
- Epidemiologically sound
- Grounded in bioforensic analysis
- Support findings of fact and legal determinations
- Closely coordinated efforts [science & law]

Investigation: Two Tracks Require Close Coordination

- Public Health
 - [epidemiology, laboratory testing, health communications, interventions]
- Law Enforcement
 - [evidence collection, chain of custody, samples, intervention dependent on circumstances]

Public Health & Law Enforcement

- Teamwork focus on common concerns but with specialized investigation/response capabilities
- Evidence from criminal event or emergency
- Emphasis on timeliness - early identification
- Key Concerns [protect public, contain disease spread, assemble all data on criminal activity or attack, protect first responders, develop strategy for those exposed or at risk, link disease to those responsible for releasing it]

Indicators of an Unusual Outbreak

- Detection [incidence and spread far exceed cases expected for time, place or person]
- Disease Type [alien introduction, manifests unusual symptoms, rates of infectivity]
- Other characteristics [number exposed, regional dispersion, methods of exposure, sensitivity, transmissibility; WHO criteria]

Public Health Investigative Response

- Detect outbreak via surveillance and ad hoc reports
- Conduct investigation
- Confirm diagnosis [case definition/identify cases]
- Design study [interview questions and lab tests]
- Analyze data [case distribution by time, place, person, risk]
- Draw inferences regarding causality [agent transmission, vehicle, mode]
- Rule out naturally occurring diseases
- Intervene to interrupt transmission and treat victims [vaccination, Quarantine, restriction]

Law Enforcement Response

- Gather evidence—assess continuing threat
- Establish evidence collection, handling, analysis, transportation, protection protocols

- Integrate documents, witness statements, medical information and other information
- Develop and Implement lawful containment strategy
- Implement interdiction and protection plans

Combined Investigative Authorities

Public Health and Law Enforcement should have:

- autonomy to plan and implement investigation
- authority to select team, resources, equipment
- coordinated access to sites, samples, and persons
- power to gather, extract information
- consultations with experts / industry reps
- detainment, restriction and quarantine powers
- rights to limit public release of sensitive information

Investigative Tools

- Medical, diagnostic [laboratory]
- Epidemiology
- Bioforensic
- WHO Global Alert and Response [FAO –OIE]
- WHO Preparedness for Deliberate Epidemics

Investigative Team

- Medical [Public Health – Epidemiology - Lab]
- Law Enforcement [investigation – information]
- Laboratory Experts in Bioforensics
- BW and Infectious Disease experts
- Program Manager – team leader

Investigative Resources

- WHO expertise
- International Experts
- National Disease and Public Health experts
- Cooperative Foreign Affairs Ministries

Investigative Issues and Challenges

- Global biosafety standards [future biosecurity rules]
- Recognized attribution standards/ benchmarks
- Systems to certify lab and lab staff expertise
- Establish investigation / collection protocols
- Strengthen global surveillance [early detection]
- Build national epidemiological investigative teams
- Build universal pathogen database [enhance warning]

Investigations

- Must reflect best scientific protocols
- Must incorporate best investigative methods

- Must include best law enforcement practices
- Must exhibit objectivity and accuracy

9. The Laboratory Response Network

LRN Mission

The LRN and its partners will maintain an integrated national and international network of laboratories that can respond quickly to acts of chemical or biological terrorism, emerging infectious diseases and other public health threats and emergencies.

LRN Laboratories

- 120 federal, state and local labs in 50 states and abroad
- National labs – CDC, military – perform definitive testing.
- Reference labs – BSL3 labs capable of confirmatory testing for agents such as *B. anthracis*, and *C. botulinum* toxin.

Focus Area C Funding

- Focus Area C is the BT lab component of CDC's BT cooperative agreement with the 50 states
- \$286 million since 1999 for laboratory renovation, personnel, equipment, and training
- Other focus areas include epidemiology, lab capacity for chemical agents, and risk communication.
- \$2.1 billion in total BT Cooperative Agreement funding to date

Provided to Each LRN Lab: Information Technology Support

- Provides secure access for more than 1,000 LRN Lab workers
- Secure communications on emerging and emergency issues
- Order reagents
- View protocols for PCR and TRF assays
- Report and review proficiency tests
- Receive periodic updates regarding reagent availability, etc.

Partnerships

Founding Partners

- CDC
- Association of Public Health Laboratories
- The Federal Bureau of Investigation
- The Department of Energy

Partnerships Shape the Scope of the LRN

- International Laboratories – LRN membership includes labs in Australia, Canada, and UK;

- Chemical – LRN is working with EPA and CDC's NCEH to build testing capacity for chemical agents.
- Food and Water – LRN includes food and water testing labs to guard against contamination
- Veterinary labs –The National Animal Health Laboratory Network through USDA's Animal and Plant Health Inspection Service (APHIS), and the American Association of Veterinary Laboratory Diagnosticians

Partners in All Facets of Biological and Chemical Terrorism Preparedness and Response

- The American Association of Veterinary Laboratory Diagnosticians
- The American Society for Microbiology
- The Environmental Protection Agency
- U.S. Department of Agriculture
- U.S. Department of Defense
- U.S. Department of Energy
- U.S. Food and Drug Administration
- The Department of Homeland Security

Ready to Respond

In the event of a terrorist act or other public health emergency, the LRN is poised to:

- Test thousands of clinical specimens and environmental samples using its multi-level network of state, food testing, clinical, veterinary, military, and federal labs.
- Coordinate response of CDC, law enforcement agencies, public health, and others.
- Accept and transfer specimens to appropriate facilities, including the CDC where definitive testing can be done.
- Assure a rapid laboratory response to any public health emergency.
- Measure human exposure to toxic chemicals using analytical tests on clinical specimens

LRN Formula for Success

- Unified operational plan
- Standardized protocols and tests
- Secure communications
- Molecular diagnostics
- Rapid response and reporting
- Safe, secure laboratories
- Trained laboratorians
- Coverage for human, animal, food, environmental specimens
- CDC coordinated support and oversight
- Quality laboratory results

10. An outbreak of an exotic Orthopoxvirus in North America: Monkeypox 2003

U.S. Research and Preparedness Activities: Smallpox

- Research Agenda based on IOM report “Future Needs for Live Variola Virus”: genome sequencing, animal models, antivirals
 - Outcome: development of rapid tests for orthopoxviruses, available at Laboratory Response Network
- Preparedness Planning:
 - Surveillance, disease recognition, vaccination, infection control, specimen collection, communication, environmental

Initial orthopoxvirus dx (as applied to case samples)

- E9L R-T PCR Old World orthopox (non-variola) +
- E9L R-T PCR variola virus-specific -
- CrmB R-T vaccinia virus-specific -
- B6R R-T monkeypox virus-specific +
- E9L standard PCR multiplex (mpox +, others -)
- HA and ATI standard PCR/RFLP (mpox +, others -)

Summary (II)

- Outbreak the result of rapid global commerce in exotic captive animals
- Emerging zoonosis
- Transmission to novel reservoir-vector species (events?)
- Potential establishment of a North American reservoir (e.g., PD’s)?
- Genomic sequence gives insights into virus characteristics
- Greater need to understand disease in African (vaccine preventable*) and reservoir host range(s)

11. Emergency Management for Public Health: Working Together for Effective Response

Goal Is to Enhance Preparedness for Bioterrorism and Infectious Disease Outbreaks

Through sharing of concepts and methodologies of the public health community and the emergency management community.

Concepts in Public Health Emergency Response: Areas of Joint Interest for Public Health and Emergency Management

- Threat recognition
- Bioforensics
- Epidemiological Investigation
- Medical Surge Capacity
- Preventive Actions
- Public information
- Community Support
- Use of New Technologies
- Legal Issues in Emergency Response

Threat Recognition Requires Flexibility

- Bioterrorism agents and routes for attack
 - May be public and obvious
 - May be covert with identification from sampling and reporting
- Surveillance methods
 - Human symptom surveillance
 - Human syndrome surveillance
 - Agricultural surveillance
- Use of laboratories
 - Resources and procedures
 - Rapid-response mobile laboratories
 - Biosafety and biosecurity

Bioforensics Can Help Distinguish Terrorist Attacks from Other Outbreak Causes

- Hallmarks of human bioattack
 - Organism identity and strain
 - Pattern of occurrence
- Hallmarks of agricultural bioattack
 - Organism identity and strain
 - Pattern of occurrence
- Case study: 2001 anthrax attacks in the United States

Epidemiological Investigations Trace Disease Transmission Backwards and Forwards

- Relationship between disease investigation and disease control
- Techniques for tracing disease origins
- Techniques for projecting population at risk

Medical Surge Capacity Requires

- Advance Planning

- What is needed: medical resources of all kinds – facilities, medical staff, support staff, laboratories, pharmaceuticals, supplies, personal protective equipment.
- Where will it come from:
- Neighboring regions
- Neighboring countries
- International organizations
- Public / private organizations
- Advance planning is essential to identify potential needs, identify sources, anticipate logistics, and secure agreements.

Effective Preventive Actions Require Cooperation and Coordination

- Prophylactic medical techniques
 - Effective use of antibiotics and vaccines (protection factors, time constraints, side effects, cost issues, etc.)
 - Targeting populations at risk
 - Stockpiling of supplies
- Protection of medical and public health staff
- Use of restrictions on contact
 - Isolation and quarantine
 - Restrictions on public gatherings
- Use of drills and exercises involving medical, public health, and emergency management personnel

Public Information Can Build Public Trust and Cooperation during Emergencies

- Public perception of risk
- Enhancing public cooperation to implement preventive actions
 - Public education in advance of outbreaks
 - Spokesperson credibility during emergencies
 - Securing compliance with public preventive measures
 - Minimizing public misinformation by maintaining contact
 - Responding to rumors

Community Support: Dealing with Secondary Effects of Disease and Quarantine

- Disease can lead to secondary effects that multiply the toll, particularly in poor areas with little reserves.
- Quarantine or isolation can disrupt economic lifelines.
- Advance planning may help minimize disruption:
- Identify possible problems
- Plan for alternate sources of critical supplies
- Community support can avoid refugee issues and concomitant risk of disease spread.
- Planning overlaps with “ordinary” disaster planning.

National and International Legal Issues Will Shape Effective Emergency Response

- Authority for protective action and problems of coercion
 - Administration of drugs and vaccines
 - Quarantine and isolation
- Preserving evidence and chain of custody during investigations

- International disease reporting
- Current / proposed International Health Regulations
- International travel restrictions
- Issues affecting international aid

New Technologies Can Improve Outbreak Emergency Response

- Sensors and detection equipment
 - Wide-field sensing for specific agents.
 - Detection equipment for use by first responders or health officers at a specific location.
- Laboratory analysis equipment
- Syndromic monitoring algorithms and information sharing systems
- Communication technologies -- infrastructure and security requirements
 - Health Alert Network
 - Epi-X

Specialized Training

Public Health Emergency Preparedness Course

Scope Includes Bioterrorism and Infectious Disease Outbreaks

- Focus on prevention and control of disease outbreaks.
 - Terrorist origin of outbreak may not be clear.
 - Preparation for naturally-occurring outbreaks is similar to preparation for bioterror attacks.
- Include food-borne pathogens.
 - There is precedent for bioterrorist use of food contamination.
 - Naturally-occurring outbreaks also a concern.

Training Crosses Public Health / Emergency Management Boundaries by:

- Providing background on public health response for emergency managers.
- Providing background on emergency management for public health officials.
- Presenting materials on response actions where the two must work together.
- Incorporating tabletop exercises to demonstrate the effectiveness of working together.

Emergency Management for Public Health: Working Together for Effective Response

12. Public Health Emergency Preparedness: An Integrated Approach

Introduction

- The U.S. government has been involved with public health preparedness for bioterrorist attacks against U.S. since 1999
- These efforts have greatly accelerated since September 11, 2001
- Biodefense preparedness and response planning involves many components and stakeholders

Overall Goal: HHS Bioterrorism Program

To ensure sustained public health and medical readiness for our communities and our nation against:

- bioterrorism
- infectious disease outbreaks
- other public health threats and emergencies

Biological Agents Meriting Priority Attention

- Category A
 - *B. anthracis*, *Y. pestis*, *C. botulinum toxin*, *F. tularensis*, Viral Hemorrhagic Fevers, *Variola major*
- Category B
 - *C. burnetii*, *Brucella sp.*, *B. mallei*, alphaviruses, Ricin toxin, SEB + additional food & waterborne pathogens
- Category C
 - Nipah & hantaviruses, multidrug-resistant TB, yellow fever, & other agents

Agents of Concern

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Provides for the regulation of certain biological agents and toxins by the Dept. of Health & Human Services and U.S. Dept. of Agriculture

- HHS Select Agents
- USDA-HHS Overlap Agents
- USDA High Consequence Livestock Pathogens and Toxins

Objectives of U.S. Public Health Emergency Preparedness Program

- Develop critical public health infrastructure and core capacities to ensure communities and states can detect and control infectious diseases
- Enhance capacities for early disease detection and control, receipt and delivery of antibiotics and vaccines, strengthening laboratory systems
- Develop effective risk communication and information dissemination strategy to address community needs

Objectives of U.S. Public Health Emergency Preparedness Program

- Lead a national bioscience research and development effort related to civilian biodefense

- Coordinate medical and public health preparedness with other efforts at the community, State, and Federal levels
- Train a public health and workforce for bioterrorism preparedness and response
- Ensure community and regional health care systems are prepared for medical and psychological needs of victims as well as the “worried-well”

Public Health’s Tiered System of Response

- fg

Content of Work Plans

- Documentation indicating achievement of critical benchmarks
- Brief proposals for other objectives:
 - plan for approach
 - measurable milestones
 - estimated budget
- Action, well-defined and achievable objectives
- Measurable outcomes that indicate enhanced preparedness and capacity to respond

Examples of Priority Benchmarks

- Designate senior public health official to serve as Executive Director of the BT Program
- Advisory committee to include broad range of representatives (public and private sector)
- Plan for dissemination of health information
- Plan for receipt and delivery of material from the National Pharmaceutical Stockpile
- Evaluate disease reports on a 24/7 basis
- Assess training needs
- Ensure working relationships and communication among all laboratory levels

Public Health’s System of Preparedness, Response, and Recovery Defining Public Health Readiness Conceptual Framework

13. Human Disease Surveillance in the United States

Public Health Surveillance

Systematic, ongoing:

- Collection
- Analysis
- Interpretation
- Dissemination
- Link to public health practice

Uses of Public Health Surveillance

- Estimate magnitude of a problem
- Determine characteristics of a problem
- Portray natural history of a condition
- Detect clusters and epidemics
- Track health behaviors and practices
- Stimulate research
- Evaluate prevention and control measures
- Facilitate program implementation

Surveillance Information Sources

- Clinical records
- Administrative/Billing records
- Personal surveys
- Environmental surveys
- Public safety records
- Vital records
- Laboratories

Opportunities for Change

- Evolving technology
- Increasing use of clinical electronic information systems
- Enhancing security/confidentiality
- Funding

Vision for National Electronic Disease Surveillance System (NEDSS)

- Ongoing, automatic capture and analysis of data
- Use data that are already electronic
- System focused on data sources, not disease specific independent systems
- Integration of public health & healthcare

National Electronic Disease Surveillance System (NEDSS)

- Browser-based data entry over Internet
- Person-centric
- Case investigation capabilities

- “industry” data and architecture standards
- Electronic Laboratory Results messages (Health Level 7 format) can be received
- Security that meets HIPAA standards

NEDSS Base System

NEDSS compatible system for state and local use developed by an experienced web software developer (Computer Sciences Corporation)

- Also useful as a specific implementation of NEDSS e.g. standard messages, database model
- Version 1.0 includes 93 notifiable diseases, and modules for vaccine preventable diseases, hepatitis, bacterial meningitis and pneumonia
- Now at Version 1.1.1; includes expanded data entry capacity, reporting capacity, locally defined fields

NEDSS Process

- 50 states, funded for NEDSS: 43 started with Assessment & Planning phase in September 2000
- FY2003 NEDSS grants: 31 propose NEDSS Base System; 26 NEDSS compatible approach
- September 2002: Public Health and Social Services Emergency Fund provides >\$1 billion for state and local public health preparedness capacity
 - guidance from CDC and HRSA to use PHIN standards for IT investments
 - Guidance explicitly includes NEDSS as part of surveillance
- September 2003: second year Preparedness funding
 - HRSA grants \$498 million; CDC \$870 million

NEDSS Site Status as of 8/11/2004

- Surveillance approaches for rapid detection
- Informed alert health care provider notifies local or state health department 24/7 contact
- Routine public health surveillance system detects an aberration
 - National Electronic Disease Surveillance System (NEDSS) designed to move surveillance to web, accept data from electronic healthcare databases
- Healthcare databases and novel data sources (veterinary labs, retail supermarket sales, business absentee data, etc) analyzed or scanned with various aberration detection algorithms
 - Biosense application
 - Systematic evaluation of utility needed

BioSense - Principles

- Early event detection is critical for Bioterrorism management and response
- The most useful tools will be dual use; Bioterrorism capable and regularly exercised for “routine” public health activities
- Multiple data sources should be co-ordinated to facilitate signal evaluation and reduce user burden
- Both diagnostic and pre-diagnostic (syndromic) data exist in electronic form in many yet untapped health-related data stores

What is Biosense?

- Near real-time data access
- Analysis capabilities at local, state and national levels
- Shareable outbreak detection algorithms and analytic capabilities
- National coverage

BioSense System I

BioSense System II (proposed)

14. Syndromic Surveillance

Need for Improved Surveillance - Syndromic Surveillance Definition

Disease surveillance that emphasizes

- Timely, complete, automated data collection
- Statistical tools to recognize outbreaks
- Use of data that reflect disease behaviors early in clinical course, before a diagnosis has been assigned

Potential Syndrome Groups

- Respiratory (cough, pneumonia)
- Gastrointestinal (vomiting, diarrhea)
- Neurologic (meningitis)
- Botulism-like (dysphagia, descending paralysis)
- Hemorrhagic (petechiae, bruising)
- Rash (vesicular rashes, smallpox-like)
- Fever/Malaise/Sepsis (unspecified fever)
- Lymphadenitis
- Isolated Cutaneous Lesion
- Coma/Sudden Death

Use in BW/BT

Detect increase in case counts earlier using

- Pre-clinical data
 - Absenteeism, animal health, public transportation use
- Early clinical data
 - Over-the-counter pharmacy sales
- Clinical data
 - Outpatient and emergency room visits, lab tests ordered

Drug Sales and Patient Visits, School Absenteeism - System Components

- Continuous data stream
 - Quality issues
 - Timeliness
 - Privacy protected
- Automated analysis tools
- Access
- Visualization

Using Pre-existing Data, Using Newly Collected Data - System Outputs

- Counts or rates of disease or disease indicators
- Geographic maps
- Demographic information
- Personal identifiers for outbreak investigation

Dual Use

Must be able to detect naturally occurring disease outbreaks

System Performance

- Designed to detect disease outbreaks earlier than most existing systems
- Provide demographic information for outbreak investigation
- Provide information for leaders and risk communicators
- Prompt more diagnostic testing

System Performance

- Can't detect every type of outbreak
 - Very small or widely dispersed
 - Large, sudden or severe outbreaks often reported through traditional means
- Many hypothesized or actual BT outbreaks may not be detected by syndromic surveillance
 - May still assist with outbreak monitoring and decision on allocation of scarce resources
- Most specific data sources are those that occur later in clinical illness

Recommendations

- If high quality data already exists, or can be cheaply obtained, it is not expensive to implement a syndromic surveillance system
- Must be aware of limitations of outbreak detection
- Use existing analysis and statistical algorithms for appropriate data sources

15. Training Infrastructures and Their Roles in Outbreak Surveillance

Background

- Surveillance for outbreak detection and response
- Outbreaks
 - complex
 - unpredictable in scope, severity and timing
- Rapid need for broad expertise and capacity
 - Epidemiology and laboratory
 - Clinical medicine (human and veterinary)
 - Communication
- Coordination
 - Government and private sector
 - NGO's and international concerns
- Preparedness

Training Needs: World Health Organization (WHO)

Integrated Disease Surveillance and Response, WHO Consultation, Geneva, 22-24 October 2003

- Clinical and public health practices
- Laboratory and epidemiology capacities
- Data structure compatibility and standardization
- Surveillance training in clinical medical and public health education
- Building skills and competencies of implementers
- Ensuring access to system information
- Improving exchange of relevant, quality information
- Networking and partnerships among systems

www.who.int/csr/labepidemiology/projects/recommendations

Training Needs: TOPOFF 2 Exercise

Purpose: to test US domestic incident management capability by exercising plans, policies, procedures, systems, and facilities of federal, state, and local response organizations against integrated terrorist threats (Chicago, Seattle, May 2003)

- Simulated biological and radiological agent releases
- Improved communication and coordination systems needed
- Emergency command centers
- Future anticipated exercises may involve more international partners

U.S. Government Overseas Training Infrastructures

- Field Epidemiology Training Programs (HHS/CDC)
- International Emerging Infections Program (HHS/CDC)
- EPI-INFO (HHS/CDC)
- PHRplus (USAID)
- DoD overseas medical laboratories
 - Thailand
 - Peru

- Indonesia
- Egypt
- Kenya

DoD Overseas Laboratory Training Infrastructures

- Clinical research cooperative with host country Ministries
- Disease surveillance
- Laboratory diagnostic equipment and training
- Epidemiology training and outbreak response
- Infection control and prevention

DoD Overseas Laboratory Training Infrastructures

- ASEAN-disease-surveillance.net
 - Communications
 - Networking
 - Training
- Early Warning Outbreak Recognition System (EWORS)
 - Syndromic outbreak detection
 - Associated with epidemiology, laboratory, clinical strengthening
 - Enhanced communication with health officials and experts

Training Infrastructures

- Multidisciplinary investigative teams
 - EPI-AIDS (HHS/CDC)
 - DoD overseas medical laboratory based Epi-CONs
 - Investigations involving host country professionals and health officials
- Rapid laboratory detection and diagnosis in outbreaks
 - Malaria
 - Typhoid fever
 - Brucellosis

Conclusion

- Surveillance systems: information for action
- Training reinforces and improves capacities
 - Clinical and veterinary
 - Epidemiology and public health
 - Laboratory diagnostics and outbreak detection
- Communication and coordination systems
 - Gaps identified by training exercises
 - Training facilitates systems integration
- International cooperation by US Government

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16. West Nile Virus in the U.S.: A Case Study

West Nile virus

- Mosquito-borne virus belonging to the genus *Flavivirus*
- Member of the antigenic complex including St. Louis, Murray Valley, and Japanese encephalitis viruses
- Until recently, found only in the eastern hemisphere including all of Africa and the Middle East, parts of Europe, Russia, India, and Indonesia

West Nile Virus

- Transmission cycles involving a variety of wild birds and *Culex* species mosquitoes are thought to be the primary mechanism for maintenance of the virus in endemic areas.
- Humans and most other non-avian species are incidental hosts, failing to produce viremias of sufficient magnitude to infect susceptible mosquitoes.
- Degree of virulence of this virus among vertebrate hosts is variable, ranging from inapparent to lethal depending on species, age, and other factors.

West Nile Virus in the US

The identification of a newly emerging infectious disease within a few months was due to the combined, considerable efforts of scores of individuals and several agencies in the animal and public health fields and in academia. Here is an overview of the key events that occurred.

The animal outbreak

- June veterinarian in Queens treated several birds with neurologic symptoms
- Reports of dead birds increased through July and August
- Mid-August dead wild birds necropsied by New York State Department of Environmental Conservation
- Late August- caged birds affected at Bronx and Queens zoos

Human Outbreak

- Late August – specialist in infectious disease noticed that Queens hospital had an abnormally large number of suspected encephalitis or meningitis, and several of the patients had an unusual pattern of muscle weakness.
- City health officials contacted the state health department and CDC for help.

Human Outbreak

- September 3, initial serology test results were interpreted to be positive for SLE (IgM-capture ELISA for antibodies to the common N A arboviruses)
- Mosquito control measures begun immediately.
- September 9 and in the following days, NY State Dept of Health received conflicting test results, weakly positive and negative test results for SLE (ELISA)

Animal disease outbreak

- Thousands of dead crows were being found all over New York City.
- Wildlife disease archives had never recorded a crow die off in the United States.
- Dead crows sent to the NY State's Department of Environmental Conservation (gross necropsies were performed, but no laboratory assays were conducted).

The Animal Outbreak

- City and State health workers, the public, and wildlife veterinarians questioned whether the deaths of large numbers of birds and the human encephalitis cases might be connected
- Health officials said they considered the two outbreaks to be unrelated because SLE does not kill birds.

The animal health outbreak

- Zoo veterinarians and wildlife pathologists enlisted help from USDA (NVSL) and the US Geological Survey laboratory.
- Mid-September- both labs concluded that bird disease was caused by a flavivirus, but not SLE
- Connecticut Agricultural Experiment Station isolates a flavivirus from an encephalitic crow and from pools of mosquitos
- U.S. Army Medical Research Institute of Infectious Disease also found a flavivirus in Bronx zoo specimens

Human and Animal Disease Investigations Converge

- September 15, State health Department shared pathology specimens with academic researcher from California
- September 20, 1999 USDA, NVSL sent Bronx zoo isolates to CDC Fort Collins arbovirus lab
- Diagnosis of West-Nile-like virus announced

Convergence of Human and Animal Investigations

- The analysis of the West Nile outbreak began as two separate investigations: one of sick people, the other of dying birds
- A consensus that the bird and human outbreaks were linked (which was key to identifying the correct diagnosis) took time to develop and was initially dismissed by many involved in the investigation
- When the bird and human investigations converged several weeks after the initial diagnosis, and after laboratory research was launched independently to explore other possible causes, the link was made and the virus was correctly identified.

“Neon needles” in a haystack

- Laboratory testing of dead birds has provided the first confirmation of viral activity in most areas.
- The surveillance factor most closely associated with the number of human cases has been the dead crow density.
- Viral isolation from birds is easier than from humans because of the higher viral titers achieved in birds.

West Nile Virus

- Brain hemorrhage
- Splenomegally
- Encephalitis
- Myocarditis

The surveillance system that has developed in North America (because of the utility of testing dead birds for the rapid detection of WN virus particles) has been a unique integration of public health and wildlife health agencies

Key Lessons

- Many of threat agents are zoonotic agents
 - 70% of the emerging diseases are zoonotic diseases
 - Links between public and animal health agencies are vital for effective diagnosis of emerging diseases and potential threat agents
-