

Unveiling the Principles of Law during Public Health Emergencies

Clinician Outreach and Communication Activity (COCA) Conference Call April 23, 2013

Objectives

At the conclusion of this session, the participant will be able to accomplish the following:

- ❑ Discuss the state and federal governments' role in responding to a public health emergency.**
- ❑ Discuss the underlying legal authorities that permit the government to take specific actions during a public health emergency.**
- ❑ Describe CDC's legal response to specific public health emergencies, including H1N1.**

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AAVSB/RACE: This program was reviewed and approved by the AAVSB RACE program for 1.2 hours of continuing education in the jurisdictions which recognize AAVSB RACE approval. Please contact the AAVSB Race Program at race@aavsb.org if you have any comments/concerns regarding this program's validity or relevancy to the veterinary profession.

TODAY'S PRESENTER



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Centers for Disease Control and Prevention

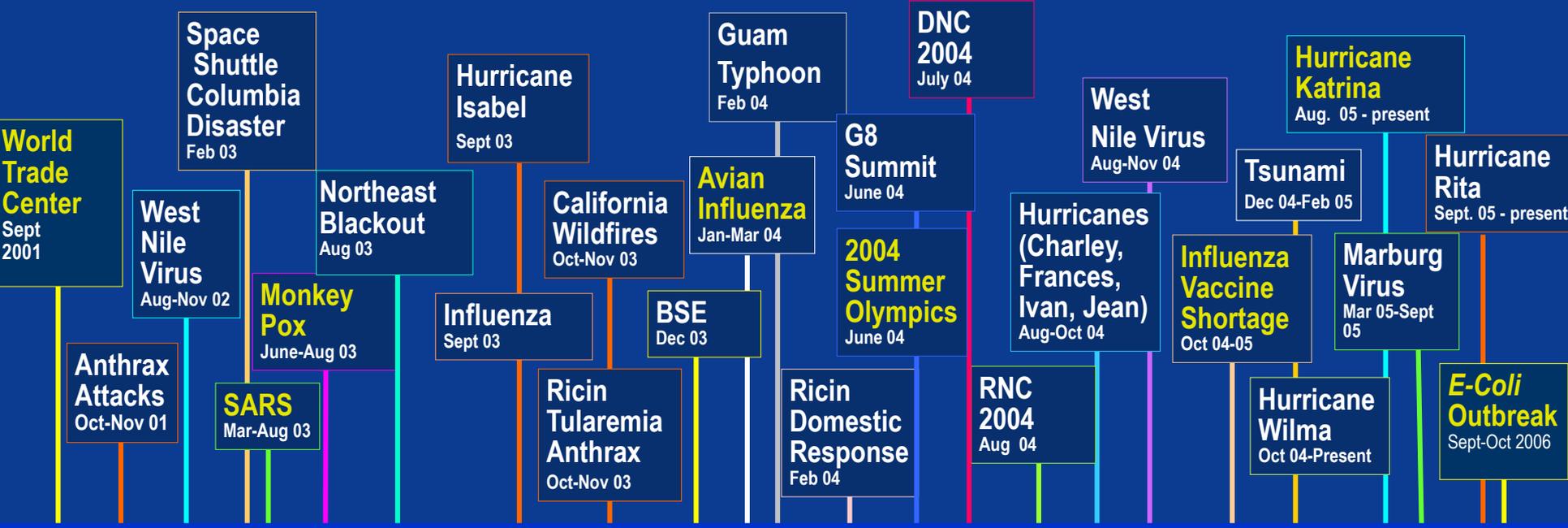


Recent Public Health Emergencies and the Public Health Response

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CDC 24/7



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CDC Responds to Public Health Challenges: Some Recent Examples



- **>750 outbreak and field investigations (2010–2011)**
 - In 49 states, 5 U.S. Trust Territories, and 35 countries
- **Foodborne outbreaks**
 - In 2011, helped state and local health agencies investigate 222 outbreaks
- **During the H1N1 pandemic in the United States CDC helped prevent**
 - 713,000–1.5 million influenza cases
 - 12,300–23,000 hospitalizations
 - 620–1,160 deaths

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Monkeypox

- Rare viral disease related to, but considered less infectious and milder than, smallpox
- Introduced to the United States in 2003 through a shipment of African rodents
- In the U.S., prairie dogs infected by rodents from Africa may become vectors for transmitting the virus



Monkeypox & Gambian Giant Rats

A shipment of African rodents—including Gambian giant rats—was the probable source of the introduction of monkeypox into the United States.





The Federal Response to Monkeypox



June 11, 2003: CDC and FDA issued a joint order announcing an immediate embargo on the importation of all rodents from Africa and prohibiting the transportation, distribution, or release of prairie dogs and specified African rodents within the United States.

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CDC's Legal Authority to Respond to Public Health Emergencies

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Who is in Charge?

- States primarily responsible for controlling disease spread within their borders
- Federal government responsible for controlling disease spread from foreign countries and interstate
- Federal government has special obligations internationally and with respect to Indian Tribes

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Legal Authorities: Case Law

- The U.S. Supreme Court
 - ◆ Required Vaccination
 - Jacobson v. Massachusetts (1905)



Legal Authorities: Statutory Law

- Determination of a Public Health Emergency
 - ◆ Public Health Service Act § 319; 42 USC § 247d

- Quarantine Authority
 - ◆ Public Health Service Act § 361; 42 USC § 264
 - ◆ 42 CFR 70 and 71
 - ◆ Executive Order 13295, as amended by 13375

- Federal-State Cooperation
 - ◆ Public Health Service Act § 311; 42 USC § 243

- International Cooperation
 - ◆ Public Health Service Act § 307; 42 USC § 242f

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319 Public Health Emergency Declarations

- HHS Secretary may declare “public health emergency” under Section 319 of PHS Act
- Requires consultation with public health officials as necessary
- 90-day limit, may be renewed, notify Congress



319 Public Health Emergency Declarations



- HHS Secretary may take such action as may be necessary to respond to PH emergency
- “Public health emergency fund” made available to Secretary
- Authority to appropriate such funds as may be necessary
- Actual appropriations may not exist



Options Pursuant to a 319 Public Health Emergency Declaration



- Waive certain sanctions that arise from noncompliance with HIPAA
- Waive or modify provisions of EMTALA (Emergency Medical Treatment and Active Labor Act)
- States may request reassignment of individuals whose salaries are paid by HHS awards to work on matters related to a 319 public health emergency declaration



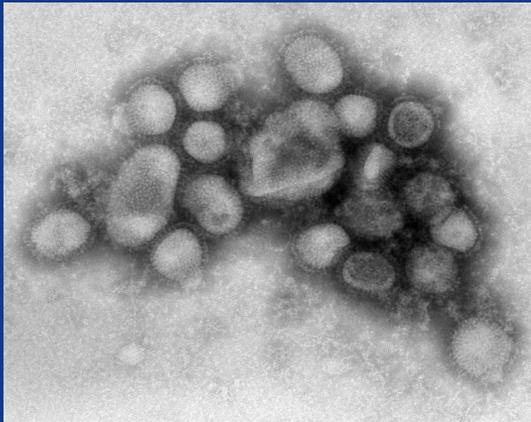
CDC's Emergency Operations Center



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Influenza 2009-2010 (H1N1)



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Determination that a Public Health Emergency Exists

As a consequence of confirmed cases of Swine Influenza A (swH1N1) in California, Texas, Kansas, and New York, on this date and after consultation with public health officials as necessary, I, Charles E. Johnson, Acting Secretary of the U.S. Department of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, 42 U.S.C. § 247d, do hereby determine that a public health emergency exists nationwide involving Swine Influenza A that affects or has significant potential to affect national security.

April 26, 2009

/s/

Acting HHS Secretary Charles E. Johnson

U.S. Declares Health Emergency

From Page 1

"It's like declaring one for a hurricane," she said. "It means we can release funds and take other measures. The hurricane may not actually hit." American investigators said they expected more cases here, but noted that virtually all so far had been mild and urged Americans not to panic. The speed and the scope of the world's response showed the value of preparations made because of the avian flu and SARS scares, public health experts said. The emergency declaration in the United States lets the government free more money for antiviral drugs and give some previously unapproved tests and drugs to children. One-quarter of the national stockpile of 50 million courses of antiviral drugs will be released. Border patrols and airport security officers are to begin asking travelers if they have had the flu or a fever; those who appear ill will be stopped, taken aside and given masks while they arrange for medical care. "This is moving fast and we expect to see more cases," Dr. Richard Besser, acting director of the Centers for Disease Control and Prevention, said at the news conference with Ms. Napolitano. "But we view this as a marathon." He advised Americans to wash their hands frequently, to cover



People took precautions on Sunday to attend Mass in Mexico City. Swine flu is believed to have killed 103 people in Mexico.



Homeland Security Secretary Janet Napolitano and Robert Gibbs, the White House press secretary, took questions in Washington on Sunday about reported swine flu cases.

One-quarter of the national stockpile of 50 million courses of antiviral drugs will be released. Border patrols and airport security officers are to begin asking travelers if they have had the flu or a fever; those who appear ill will be stopped, taken aside and given masks while they arrange for medical care. "This is moving fast and we expect to see more cases," Dr. Richard Besser, acting director of the Centers for Disease Control and Prevention, said at the news conference with Ms. Napolitano. "But we view this as a marathon." He advised Americans to wash their hands frequently, to cover coughs and sneezes and to stay home if they felt ill; but he stopped short of advice now given in Mexico to wear masks and not kiss or touch anyone. He praised decisions to close individual schools in New York and Texas but did not call for more widespread closings. Besides the eight New York cases, officials said they had confirmed seven in California, two in Kansas, two in Texas and one in Ohio. The virus looked identical to the one in Mexico believed to have killed 103 people — including 22 people whose deaths were confirmed to be from swine flu — and sickened about 1,600. As of Sunday night, there were no swine flu deaths in the United States, and one hospi-



CDC Response to H1N1

- Examples of Legal Instruments Used:
 - International Health Regulations (IHRs)
 - Public Readiness and Emergency Preparedness (PREP) Act



International Health Regulations



- International legal instrument giving rise to obligations among member countries
- Original IHR adopted in 1969 to monitor and control six infectious diseases: cholera, plague, yellow fever, smallpox, relapsing fever and typhus
- US participates in WHO pursuant to Joint Resolution of Congress authorizing President to accept membership (22 USC § 290)
- Purpose: Maximum protection of people against the international spread of diseases, while minimizing interference with world travel and trade
- Amended by WHO May 23, 2005 to address “Public Health Emergencies of International Concern” (PHEIC)
- Entered into force for U.S. on July 17, 2007 (no sanctions mechanism, but considered legally binding)



What is a PHEIC?

- A Public Health Emergency of International Concern is an extraordinary event that:
 - ◆ Constitutes a public health risk to other countries through international spread of disease, and
 - ◆ Potentially requires a coordinated international response
- List of diseases leading to immediate notification: smallpox, SARS, wild polio viruses, new subtype human influenza



IHRs: WHO Actions and CDC Response



- April 25, 2009: 1st IHR Emergency Committee Meeting; WHO determines that a PHEIC exists
- April 27: 2nd IHR Emergency Committee Meeting; WHO:
 - Raises pandemic alert to a higher level
 - Issues “temporary” recommendations:
 - Against closing borders or restricting international travel, *but* if ill, prudent to delay travel
 - Continue efforts to produce vaccine, subject to reevaluation
 - Focus efforts on mitigation measures, not containment
- April 27: CDC issues Travel Health Warning to U.S. travelers to avoid “nonessential” travel to Mexico



Public Readiness and Emergency Preparedness (PREP) Act



- Signed into law in December 2005
- Authorizes Secretary of HHS to issue a declaration to provide immunity from liability (except for willful misconduct) for certain claims
 - Death; physical, mental, emotional injury, illness, disability, condition, or fear thereof; medical monitoring; property damage or loss; business interruption
 - Causally related to development, distribution, administration or use of “covered countermeasures”
 - Against “covered persons” (PHS Act § 319F-3)
- Authorizes emergency fund in U.S. Treasury for compensation for injuries from covered countermeasures, (PHS Act § 319F-4)

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PREP Act: Covered Persons



- Manufacturers
- Distributors
- Program Planners (State, local government, tribe, others who supervise or administer countermeasure programs)
- Qualified Persons (licensed health professionals and others identified by the Secretary who prescribe, administer, or dispense countermeasures)
- Officials, Agents, Employees of all of the above
- United States

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PREP Act: Covered Countermeasures



- Qualified Pandemic or Epidemic Product
 - Drug, biological product, device against pandemic or epidemic disease (or against adverse effects of such drugs, biological products, or devices)
 - Approved, licensed, or under Emergency Use Authorization (EUA), Investigational Drug (IND) or Device (IDE) application
- Security Countermeasure
 - Drug, biological product device against harm from biological, chemical, radiological or nuclear agent (or against adverse effects of such drugs, biological products, or devices)
 - Necessary to protect public health
 - Approved, cleared, licensed, qualify for approval or licensing within eight years of federal procurement, EUA, IND, or IDE
- Product Authorized under EUA
- Additional Products – still to be determined – may also be covered

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H1N1 PREP Act Declarations

- Antivirals (Tamiflu, Relenza)
- Influenza diagnostics, personal respiratory protection devices, and respiratory support devices
- H1N1 vaccine



Scope of the PREP Act



Does the PREP Act protect persons who accidentally administer the vaccine to a child without her parent's consent?



Parker v. St. Lawrence County Public Health Dep. and Lisbon Central School



- A kindergarten student was accidentally vaccinated without her parents' authorization and her parents brought an action in State court alleging negligence resulting in battery upon the student.
- The public health department and the school claimed that the PREP Act vests exclusive subject matter jurisdiction in the federal government over all claims having a causal relationship with the administration of the flu vaccine during the inoculation program.
- The judge disagreed, arguing that the purpose of the act was to protect administrators from liability for adverse physical reactions to the vaccine, not against intentional or negligent unauthorized administration.
- St. Lawrence County Public Health Department filed an appeal. The case against the school was dismissed on other grounds.
- On 11/21/2012, the appellate court concluded that plaintiff's state law claims are preempted by the PREP Act and therefore the complaint was dismissed.

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Quarantine: A Public Health Necessity

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Quarantine: Constitutional Design

- State and local governments have primary responsibility for public health
- Public health is a “police power” retained by the States under the 10th Amendment
- Federal authority is derived from the constitutional authority to regulate foreign and interstate commerce, and among the Indian Tribes



Public Health Service Act Section 361



- Codified at 42 U.S.C. § 264
- HHS Secretary may authorize regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into U.S. or from one state or possession into another
- Regulations authorize measures, e.g., inspection, sanitation, destruction of animals or articles
- “Apprehension, examination, conditional release” of individuals for purposes of preventing communicable diseases specified in an Executive Order

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Federal Quarantine/Isolation

- Communicable Disease listed in Exec. Order 13295
 - ★ cholera, diphtheria, infectious TB, plague, smallpox, yellow fever, viral hemorrhagic fevers (Ebola), SARS, and influenza that are pandemic or could become so
- Two separate regulation parts:
 - ★ Part 70 = domestic interstate quarantine
 - ★ Part 71 = travelers seeking entry into the US



Questions?



Contact Information

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Centers for Disease Control and Prevention Atlanta, Georgia

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<http://www.cdc.gov/TCEOnline/>

Those who participate in the COCA Conference Calls and who wish to receive CE credit/contact hours and will complete the online evaluation by **May 24, 2013** will use the course code **EC1648**. Those who wish to receive CE credits/contact hours and will complete the online evaluation between **May 25, 2013** and **Apr 22, 2014** will use course code **WD1648**. CE certificates can be printed immediately upon completion of your online evaluation. A cumulative transcript of all CDC/ATSDR CE's obtained through the CDC Training & Continuing Education Online System will be maintained for each user.

Thank you for joining!
Please email us questions at
coca@cdc.gov

Emergency Preparedness and Response

Emergency Preparedness & Response

Specific Hazards

Preparedness for All Hazards

Clinician Resources

COCA Conference Calls

Conference Calls - 2013

► **April 23, 2013**

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What You Can Do

Blog: Public Health Matters

What's New

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Unveiling the Principles of Law During Public Health Emergencies

 = Continuing Education

Date: Tuesday, April 23, 2013

Time: 2:00 - 3:00 pm (Eastern Time)

Participate By Phone

Dial In Number: 1-888-233-9077

Passcode: 2072335

Participate By Webinar:

<https://www.mymeetings.com/nc/join.php?i=PW8407556&p=2072335&t=c>

Presenter(s):

  **Heather Horton, JD, MHA**
Senior Attorney
HHS Office of the General Counsel
Centers for Disease Control and Prevention

Overview:

The possibility of public health emergencies arising in the United States concerns many people in the wake of the recent hurricanes, tsunamis, acts of terrorism, and pandemic influenza. In addition to identifying critical infrastructure and key resources to incorporate in an emergency response plan, it is important to understand the balance between the rights of individuals, legalities for treating patients, and the needs of the community. Please join us for this COCA Call where a CDC subject matter expert will describe state and federal governments' role in preparing for and responding to public health emergencies.

<http://emergency.cdc.gov/coca>

Join Us on Facebook

CDC Facebook page for Health Partners! “Like” our page today to receive COCA updates, guidance, and situational awareness about preparing for and responding to public health emergencies.



The screenshot shows the Facebook interface for the CDC Health Partners Outreach page. At the top, there is a navigation bar with the Facebook logo, a search bar, and login options for Email and Password. Below the navigation bar, there is a "Sign Up" button and the text "Facebook helps you connect and share with the people in your life." The main content area features the CDC Health Partners Outreach profile picture and cover photo. The profile information includes the name "CDC Health Partners Outreach" and the location "Government Organization · Atlanta, Georgia". The "Wall" section displays a post from the CDC Health Partners Outreach page, dated Monday at 7:08am. The post text reads: "CDC is partnering with NPHIC to host a webinar July 21 (3:00pm ET) on Crisis and Emergency Risk Communication – Radiation. A subject matter expert from the Oak Ridge Institute for Science and Education (ORISE) will address key elements of communicating during a radiation disaster, share CDC research on messaging, and provide lessons learned from Japan's recent nuclear emergency. Register for this FREE webinar today!". The post includes a link to "events.720.constantcontact.com" and "CERC Webinar – July 21". Below the post, there are three likes from Jessica Guidry, Marta Lugo, and Marcy Dabziel Belvin. The left sidebar shows the "Wall" tab selected, along with "Info", "Photos", and "About" sections. The "About" section states: "Health Partners Outreach Team is with the CDC Emergency Risk Communication...". The "Likes" section shows three likes from "CDC Emergency Preparedness and Response" and "CDC".

<http://www.facebook.com/CDCHealthPartnersOutreach>