Ebola and the Law: What You Need to Know

August 12, 2014
How to Use Webex

- **Audio**: If you can hear us through your computer, you do not need to use your phone. Just adjust your computer speakers as needed.

- **Support**: If you need technical assistance, call Webex Technical Support at 1-866-863-3904.

- **Submitting Questions**: All participants are muted. Type a question into the Q & A panel for our panelists to answer. Submit your questions at any time during webinar.

- **Recording**: This webinar is being recorded. If you arrive late, miss details or would like to share it, we will send you a link to this recording after the session has ended.
Ebola and the Law: What You Need to Know

August 12, 2014
Moderator

Matthew Penn, Director, Public Health Law Program — Office for State, Tribal, Local and Territorial Support, Centers for Disease Control and Prevention

- J.D., University of South Carolina
- Research interests/areas of expertise:
  - Disease Control
  - Public Health and Bioterrorism Preparedness
  - HIPAA
  - Health Regulation
Presenter

**Brian Bird**, Veterinary Medical Officer—Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases

- M.S.P.H., Johns Hopkins University; D.V.D., Ph.D., University of California, Davis

- Research interests/areas of expertise:
  - Virus Pathogenesis
  - Vaccine and Anti-Viral Drug Development
  - Diagnostics in Outbreak Responses
Jane Jordan, Deputy General Counsel/Chief Counsel for Health Affairs, Acting Vice President for Governmental Affairs Emory University Hospital

- J.D., University of South Carolina

- Research interests/areas of expertise:
  - Patient Care/Hospital Operations
  - Patient Consents/End of Life Issues
  - Regulatory Affairs
Presenter

James Hodge, Jr., Director, Network for Public Health Law — Western Region Office, Sandra Day O’Connor College of Law

- J.D. Salmon P. Chase College of Law
- LL.M., Georgetown University Law Center

Research interests/areas of expertise:
- Public Health Emergency Legal Preparedness
- Public Health Law and Ethics
- Public Health Information Privacy Law and Policy
Ebola virus Basics

August 12th, 2014

Brian H. Bird, DVM, MSPH, PhD
Laboratory Team
CDC Ebola Response 2014
Background: West Africa Ebola Outbreak

- Largest ever recorded
  - >1,800 cases since March, 976 deaths
  - First in West Africa: Guinea, Liberia, Sierra Leone, Nigeria

- 39+ CDC staff and numerous international personnel deployed
  - Clinical Care, Data Management, Epidemiology, Health Education & Communications, Laboratory diagnostics

- Two infected U.S. aid workers returned to U.S. isolation facility
Ebola and Marburg Hemorrhagic Fevers: The Viruses

**Family Filoviridae**

- 5 species of *Ebolavirus*
  - *Sudan ebolavirus* (1976) = Sudan virus
  - *Taï Forest ebolavirus* (1994) = Tai Forest virus

- 1 species of *Marburgvirus*
  - *Marburgvirus marburgvirus* (1967)
Ebola virus Ecology

**Enzootic Cycle**
New evidence strongly implicates bats as the reservoir hosts for ebolaviruses, though the means of local enzootic maintenance and transmission of the virus within bat populations remain unknown.

**Ebolaviruses:**
Ebola virus (formerly Zaire virus)
Sudan virus
Taï Forest virus
Bundibugyo virus
Reston virus (non-human)

**Epizootic Cycle**
Epizootics caused by ebolaviruses appear sporadically, producing high mortality among non-human primates and duikers and may precede human outbreaks. Epidemics caused by ebolaviruses produce acute disease among humans, with the exception of Reston virus which does not produce detectable disease in humans. Little is known about how the virus first passes to humans, triggering waves of human-to-human transmission, and an epidemic.

Following initial human infection through contact with an infected bat or other wild animal, human-to-human transmission often occurs.

Human-to-human transmission is a predominant feature of epidemics.
Filovirus Ecology

- Marburg: reservoir is Egyptian Fruit Bats (*Rosettus aegyptiacus*)
  - Exposures to cave-dwelling bats

- **Ebola: Reservoir is UNKNOWN**
  - Bats implicated
  - Non-Human primates also develop severe hemorrhagic disease
  - Duikers, pigs (Reston)— become infected, role of transmission unknown
Clinical Manifestations- Humans

- Incubation period: 2–21 days
- Abrupt onset
  - Fever, headache, chills, malaise, and myalgia
  - GI symptoms most common: vomiting, diarrhea, abdominal pain
- Hemorrhagic symptoms in <half of cases
  - Mild: petechiae, epistaxis, ecchymosis, bruising
  - Severe: GI hemorrhage, shock, DIC
- Less commonly seen: rash (trunk, shoulders), conjunctivitis, pharyngitis, cough, hiccups
Course of Disease & Virus shedding

- Not transmissible prior to onset of symptoms
  - All body fluids can carry virus
- Virus quantity increases to death, usually 9-10 days post-onset
- If patient survives to day 14, increased chance of survival
- Convalescence: resolution of viremia/development of antibodies (seroconvert)
Clinical Care

- No specific treatments currently available
  - Vaccines, monoclonal antibodies in development
- Supportive care
  - Intravenous Fluids
  - NSAIDs (anti-inflammatories/pain control)
  - Nutritional support
  - Antibiotics to reduce secondary infection risk
Ebola Hemorrhagic Fever

Ebola hemorrhagic fever (Ebola HF) is one of numerous Viral Hemorrhagic Fevers. It is a severe, often fatal disease in humans and nonhuman primates (such as monkeys, gorillas, and chimpanzees).

More about Ebola HF »

Outbreak in Guinea, Liberia, and Sierra Leone

The Ministries of Health (MoH) of Guinea and Liberia and the World Health Organization (WHO) have reported an outbreak of Ebola hemorrhagic fever in several Guinean and Liberian districts.

• Latest CDC Outbreak Information
  Updated: July 31, 2014
  World Health Organization’s Epidemic and Pandemic alert and Response (EPR):9
  Guinea: Ebola epidemic declared, MSF launches emergency response6
  Radio spots for Outbreak

What’s New

• August 2, 2014:
  Updated: Interim Guidance about Ebola Virus Infection for Airline Flight Crews, Cleaning Personnel, and Cargo Personnel

• August 1, 2014:
  HAN: Guidelines for Evaluation of US Patients Suspected of Having Ebola Virus Disease

• August 1, 2014:
  Questions and Answers on Ebola

• August 1, 2014:
  Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals

• July 31, 2014: Level 3 Travel notices - Liberia | Sierra Leone | Guinea

Continued »

Resources

Outbreak Postings
Chronology & References
Virus Ecology Graphic
Distribution Map
Fact Sheet [PDF - 156 KB]
Fact Sheet - French Version [PDF - 82 KB]

Information For:

Working and Living Abroad
Health Care Workers
Airline Personnel
Travelers

More »
Additional CDC Public Health Law Program Resources:

http://www.cdc.gov/phlp/publications/topic/emergency.html
Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Phone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov  Web: www.cdc.gov
Institutional Response: Preparedness and Communications

Jane E. Jordan
Deputy General Counsel/Chief Counsel for Health Affairs, Emory University
August 12, 2014
Thursday, July 31, 2014

Emory University Hospital has been informed that there are plans to transfer a patient* with Ebola virus infection to its special facility containment unit within the next several days. We do not know at this time when the patient will arrive.

Emory University Hospital has a specially built isolation unit set up in collaboration with the CDC to treat patients who are exposed to certain serious infectious diseases. It is physically separate from other patient areas and has unique equipment and infrastructure that provide an extraordinarily high level of clinical isolation. It is one of only four such facilities in the country.

Emory University Hospital physicians, nurses and staff are highly trained in the specific and unique protocols and procedures necessary to treat and care for this type of patient. For this specially trained staff, these procedures are practiced on a regular basis throughout the year so we are fully prepared for this type of situation.

Media contacts:
Vince Dollard, 404-727-3366, vdollar@emory.edu
Holly Korschun, 404-727-3990, hkorsch@emory.edu

* On Aug. 1, Emory University learned that a second patient with Ebola virus infection will be transferred to Emory University Hospital the week of Aug. 3.

Ebola and the Law
If Ebola is so hard to catch using good precautions, why did two physicians die from it? @CNN
10:14 AM - 31 Jul 2014

Stay calm, everyone. The CDC has confidently assured us that there is no possible way the Titanic can ever sink. #ebola
12:29 AM - 1 Aug 2014 Stapleton, CO, United States

Emory Healthcare @emoryhealthcare
Check out these FAQs about #Ebola and Emory’s care for these patients:
http://bit.ly/1ok1txS
2:29 PM - 2 Aug 2014
My colleagues at Emory are doing an exemplary job, especially given the magnitude of this challenge. No one has guaranteed complete safety from any disease nor will they. Rightfully however, they will try to put the risk in perspective so that most people can make a reasoned assessment and deal with the risk accordingly.

Many thanks for your comments on communications around this issue. It has and will continue to be a learning process!. I’d just like to correct one point in your narrative: Dr. Gupta did not interview Dr. Ribner in the isolation unit, and while Dr. Ribner described the unit, we did not show it to media - except for one distributed photo. That interview took place in an exam room in the hospital. While Dr. Gupta (and about 1,000 other reporters) asked to see and report from the isolation unit, we denied access to all media because preparation of the unit obviously took precedence. We did provide a hospital exam room/clinical setting for the initial interviews. Many thanks for the opportunity to point this out.
Emory University Hospital Special Isolation Unit

Wednesday, August 6, 2014

Serious Communicable Disease Unit (Isolation Unit) in Emory University Hospital

Emory University Hospital has a special isolation unit, called a Serious Communicable Disease Unit, that was set up in collaboration with the CDC to house CDC scientists and others who have traveled abroad and become exposed to infectious diseases. This unit has unique equipment and infrastructure that provides an extraordinarily high level of clinical isolation with very different capabilities than are normally provided to isolate patients in other hospitals. It is one of only four such facilities in the country. This illustration above shows an anteroom for physicians and nurses, two patient rooms and attached patient support rooms and a staff dressing room. Glass windows in patient rooms allow the patient and family to see one another.

Press Conference Q&A
Ebola and the Law
Practical Considerations/Suggestions: Incident Response Team

- Assess Facts Quickly/Modify Existing Incident Response Team to Fit Circumstances
- Designate Incident Response Team and Team Leader.
- Maintain 24-hour contact information for members and alternates.
- Potential Team Members:
  - Hospital Operations
  - Crisis Management Consultant
  - PR/Communications
  - Privacy Officer
  - Compliance Officer
  - Medical Officer/Nursing
  - Hospital Administration
  - Risk Management
  - Environmental Safety
  - Human Resources
  - Customer Service/Patient Relations
  - Legal
  - Police/Security
  - Coordination with centralized emergency preparedness team
Practical Issues in Communications/ Suggestions

• Speed is key: Be transparent and timely; build trust with public
• Agree on external messaging (i.e. education of disease clinical indicators, prevention and treatment)
  – Identify spokesperson/substantive knowledge of issue/trustworthiness
• Be proactive/take steps to educate media and public
• Coordinated Communications Strategy and Timing is vital
  – Internal and external communications to patients, employees and public
    • External Resources (print and social media)
    • Call Center
    • Web Site
  – Notice to internal governance (Board of Directors)/Timing
  – Coordinate with external partners (Center for Disease Control)
  – Press conferences and/or updated written communications
Emergency Legal Preparedness Concerning Ebola Virus Disease (EVD)

James G. Hodge, Jr., J.D., L.L.M.
Lincoln Professor of Health Law and Ethics
Director, Western Region Office, Network for Public Health Law
Sandra Day O’Connor College of Law
Arizona State University
Primer Contents

» **International Legal Response Efforts**
  o World Health Organization
  o Foreign Governments

» **U.S. Legal Preparedness/Response**

» **Major Emerging Legal Issues**

» **Emergency Legal Preparedness Resources**
WHO Director-General on Ebola

“If the situation continues to deteriorate, the consequences can be catastrophic in terms of lost lives but also severe socio-economic disruption and a high risk of spread to other countries.”

— WHO Director-General Margaret Chan (August 1, 2014)

Source: telegraph.co.uk
WHO EVD Responses

» WHO leaders met with Presidents of Guinea, Liberia, and Sierra Leone in late July, calling it “a turning point in the outbreak response.”

» On July 24, 2014, WHO shifted from Level 2 to Level 3 on its Emergency Response Framework, authorizing more substantial support to affected countries.

» $100 million plan was announced on July 31, 2014.

» On August 8, 2014, with approval of WHO’s emergency committee, D-G Chan declared a Public Health Emergency of International Concern (PHEIC) pursuant to the International Health Regulations for the affected regions of West Africa.

» On August 11, 2014 WHO is convening a panel of medical ethicists to discuss the use of experimental treatments to combat the ongoing EVD outbreak.
Sierra Leone

State of Public Emergency
[7/31/14]

Liberia

State of Public Emergency
[8/6/14]

Nigeria

National Emergency
[8/8/14]

Guinea

No Formal Declaration
Select Foreign EVD Responses

» **Germany**: implemented its Ebola Emergency Plan; *strongly advises* against travel to affected countries.

» **South Korea**: issued a special travel advisory asking people to refrain from visiting affected countries; revoked invitation for 3 Nigerian students to attend a local university conference.

» **United Kingdom**: issued a travel advisory for affected countries; issued guidance to Border Force officers on how to handle unwell passengers arriving at the border.

» **Bangladesh**: issued an alert for EVD, allowing medical teams to monitor the international airports for 90 days.

» **Ghana**: Ministry of Health issued a red alert on EVD and instructed citizens to avoid public swimming pools and practice strict hygiene.
U.S. EVD Preparedness and Response

President Barack Obama:

**August 1, 2014**

“[EVD] is something that we take very seriously . . . We feel confident that the procedures we’ve put in place are appropriate . . . [T]he key is identifying, quarantining, isolating, and making sure practices are in place to avoid transmission . . .”

**August 6, 2014**

“[D]espite the fact that we have to take this very seriously, . . . this is one that can be controlled and contained very effectively if we use the right protocols . . . I will continue to seek information about what we’re learning with respect to [potential EVD] drugs going forward.”
Reported Suspected or Potential Cases of EVD Nationally (as of August 11, 2014)
U.S. EVD Preparedness & Response

» 2 American HCWs are receiving treatment for EVD in Atlanta.

» No other confirmed cases of EVD in the U.S. at present although multiple reports of suspicious or potential cases have arisen.

» No major emergency declaration by federal, state, or local authorities to date.

» DoD established a new Ebola task force to evaluate how best to support overarching national and international efforts to prevent further spread.

» DHHS and FDA have issued an EUA for a specific Ebola assay test.
EVD Tests and Therapies

» 2 American HCWs with EVD consented to and were given an experimental serum ("ZMapp") developed by San Diego based company Mapp Biopharmaceutical, Inc.

» Administration of the serum is initially attributed to health improvements among both patients after 1-2 doses.

» FDA has not issued an emergency use authorization (EUA) for ZMapp.

» On August 5, 2014, FDA issued an EUA for DoD EZ1 Real-time RT-PCR Assay to detect the Ebola virus in individuals in affected areas with signs and symptoms, or who are at risk of exposure to the virus.

» On August 7, 2014, FDA modified the hold on an investigational therapeutic produced by Tekmira Pharmaceuticals Corp. from a full clinical hold to a partial clinical hold, allowing for potential use of TKM-Ebola.
Emerging Legal Issues - Topics

- Testing
- Screening
- Treatment
- Transportation
- Liability
- Licensing
- Scope of Practice
- Allocations
Emerging Legal Issues – Examples

» Potential emergency declarations by federal authorities?
» State and local emergency declarations?
» Legal support for rapid development of EVD vaccine?
» Nature of consent needed for use of experimental treatments?
» Use of isolation and quarantine measures?
» Due process procedures to require testing for EVD?
» Patient and familial privacy implications?
» Imposition of formal travel restrictions?
» Re-entry of U.S. citizens with confirmed cases of EVD?
» Interjurisdictional deployment of volunteer HCWs?
» Respect for religious beliefs concerning treatment or burials?
» Application of EMTALA provisions amidst potential emerging cases?
» Disability status for persons with or suspected of contracting EVD?
Emerging Legal Issues – Guidance

Before Emergency Declarations

After Emergency Declarations
Crisis Standard of Care

A “crisis” standard of care applies during declared emergencies, allowing for legal adaptation to the changing circumstances and increased demands.
Emergency Legal Preparedness Info and Resources

» Network for Public Health Law Emergency Legal Preparedness Response

» CDC Traveler’s Health, Newsroom, and Emergency Preparedness and Response

» NW Center for Public Health Practice Public Health Law Training Database

» NACCHO Emergency Legal Preparedness Training Kit

» UPMC Center for Health Security

» WHO Disease Outbreak News

» National Center for Disaster Preparedness, Columbia University
Acknowledgements

» Special thanks to Kim Weidenaar, Asha Agrawal, Matthew Saria, and Rose Meltzer for their assistance with this presentation

» Questions, comments?

» Ask the Network
  https://www.networkforphl.org/ask_a_question/

» james.hodge.1@asu.edu; (480) 727-8576
Please type your questions in the Q&A panel.
Intersection of Law, Policy and Prevention
October 16 & 17 | Atlanta, GA

Attend to learn how law can be used to address some of today’s most critical public health issues.

Get more info and register at: phlc2014.org
Thank you for attending

Please join the Network for these upcoming webinars:

Advancing Infant Health: Addressing Disparities and Identifying Legal Strategies to Promote Breastfeeding
Thursday, August 21 — 1 p.m. (ET)

Legal and Policy Tools in Drug Overdose Prevention
Thursday, August 28, 2014 — 1 p.m. (ET)

More information: networkforphl.org/webinars