Real-Life Experience in Laboratory Testing of Specimens from Patients with Ebola Virus Disease

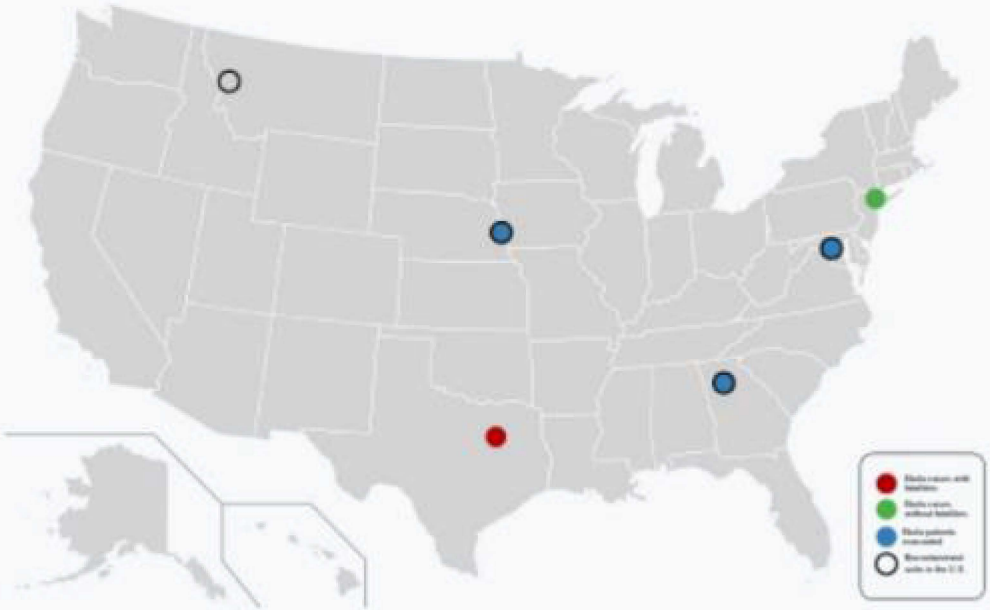
Peter C. Iwen, PhD, D(ABMM), F(AAM)
Director, Nebraska Public Health Laboratory
Professor, University of Nebraska Medical Center
piwen@unmc.edu

No Disclosures to Reveal

Equipment shown is for illustration purposes only and not intended as a CDC endorsement

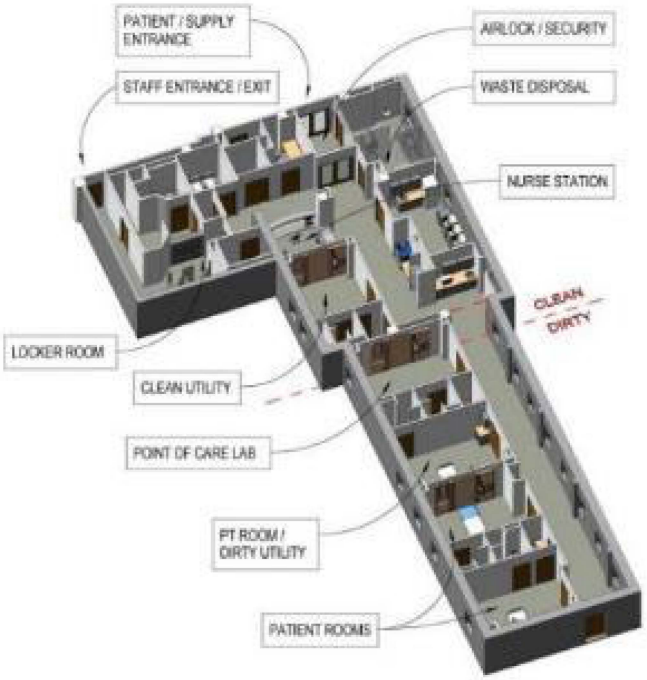
Objectives

- Historical perspective
  - Caring for patients with EVD
  - Laboratory response
  - Laboratory challenges
- What did we learn?



Map of Ebola cases and infrastructure throughout the U.S.

Cases contracted in the U.S.	2
Cases first diagnosed in U.S.	4[note 1]
Cases evacuated to U.S. from other countries	7[1]
Total cases	11[note 2]
Deaths	2[2]
Recoveries from Ebola	9[note 2]
Active cases	0



3D Illustration

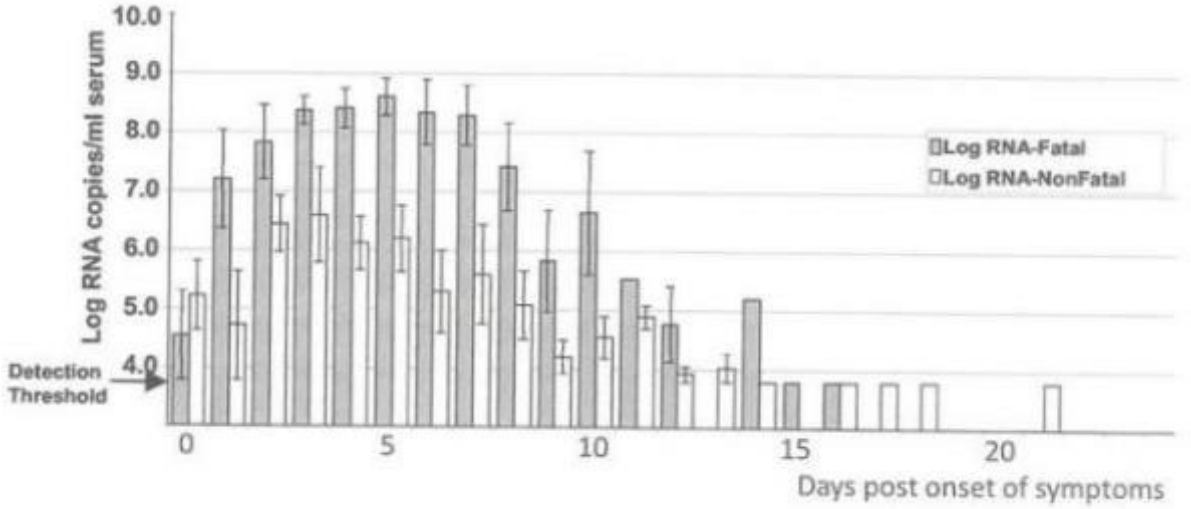
Bio Containment Unit

LEO A DALY

Risk to Handle EV-Infected Specimens

- High viral loads in symptomatic patient
  - >100,000,000 pfu/ml
- Infectious dose
  - <10 viable viral particles
- Blood micro-droplets
  - Easily contain enough virus to cause infection

Figure 1. Ebola virus RNA copy levels in sera over time from 45 Ebola Virus Disease (EVD) patients (27 fatal, 18 non-fatal)[14]



CDC document, Review of Human-to-Human Transmission of Ebola Virus

What level of risk were we willing to accept?

Knew that specimens contained Ebola virus

OSHA, General Duty Clause U.S.C. 654(a)(1), requires that employers furnish every employee a workplace that is free from recognized hazards that can cause or are likely to cause death or serious physical harm….

Table 1
Essential and Supplemental Tests Used for the Support of a Patient Infected With Ebola Virus[a]

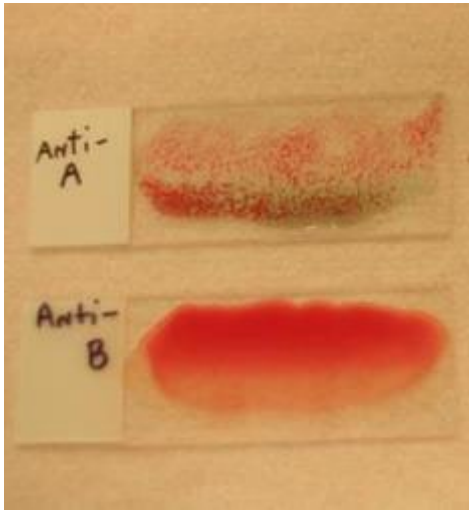
Test	Laboratory Location[b]	Centrifugation Required[c]
Essential		
CBC count with automated differential	Core	No
Basic metabolic panel	Core	Yes[d]
Magnesium	Core	Yes
Comprehensive metabolic panel	Core	Yes[d]
Ionized calcium[e]	BCU	No
Standard calcium	Core	Yes[d]
Phosphorous	Core	Yes
Cortisol	Core	Yes
Troponin	Core	Yes
Blood gases[e]	BCU	No
Lactate	Core	Yes[d]
Protime[e]	BCU	No
Partial thromboplastin time[e]	BCU	No
Platelet count	Core	No
Blood typing[f,g]	BCU	No
Culture procedures[h]	NPHL[i]	No
Molecular assay[j]	NPHL[i]	No
Supplemental		
Manual differential	Core	No
Lipase	Core	Yes
Amylase	Core	Yes
Creatine kinase total	Core	Yes
Malaria smear[k]	Core	No
HIV screen	Core	No

Be flexible!

Note: This list would need to expand to include patients without a diagnosis

Iwen, PC, et al. 2015, Amer J Clin Path, 143: 4-5

On-Site Risk Assessment Results



- Chemistry automated analyzer
  - Initial centrifugation – no sealed rotors
- Coagulation automated analyzer
  - Required open tube testing
- Blood Bank
  - Cross match required open tube centrifugation
- Biosafety cabinet not available in the core lab

Conclusion: Not all laboratory sections could safely handle specimens from a patient with the potential to have EVD.

Safety

Risk Mitigation

Based on the biological risk assessment

- Engineering Controls
  - Equipment
    - Biosafety cabinet
    - Sealed centrifuge rotors or safety cups
    - Testing instruments
  - Facilities
    - Negative ventilation
    - Dedicated space
- Administrative/work practice controls
  - Staff
    - Training
    - Limited access
  - Written safety policies
  - Medical surveillance
- Appropriate PPE

Safety

Risk Mitigation

- Equipment
  - Creating aerosols an issue
    - Inability to use automated chemistry analyzer
  - Use point-of-care instruments
  - Biosafety cabinet

Major Learning Lessons

- Developed an essential list of test
  - To meet CLIA standards
  - Testing instruments to meet safety standards (risk assessment process)
  - Opened lines of communication (important)
    - Medical staff
    - Equipment manufactures
    - CDC
- Not all tests could be performed safely
  - Alternatives
- Lab policies/procedures needed to be fluid

"Be prepared to provide optimal patient management in an environment that was safe for employees, students, and visitors."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LATEST EBOLA FEAR:
SAFETY OF LAB EQUIPMENT

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Manufacturer's responses:

1. Avoided answering questions
2. No protocols for testing HC pathogens
3. No protocols for decontamination
4. Would not service instruments
5. Invalidated warranties

Herstein, et al. 2019. Pub Health Rpts 134:332-7

Labs told to quarantine, even destroy costly devices; policies called irrational

Peter Eisler
USA TODAY

When physicians at the Nebraska Medical Center got their first Ebola case in September, they knew they'd rely heavily on sophisticated blood-test machines to monitor the man's condition. They didn't expect the virus might leave the machines incapacitated for longer than the patient.

Several leading manufacturers of high-tech diagnostic devices have alerted hospital laboratories that they will restrict service, support and warranties for equipment used to test blood and organ functions for Ebola patients. Fearing infections, some decline to have their technicians perform tuning and maintenance the expensive devices often require. Others advise labs to quarantine the equipment after use on Ebola patients or even destroy it — a policy that one company's own CEO calls "the dumbest" approach imaginable.

Hospital officials, including some involved in treating the few U.S. patients who have gotten Ebola, see many of the restrictions as irrational. They cite guidance from the Centers for Disease Control and Prevention, which advises that devices used to test biological samples from Ebola patients can be disinfected and reused safely.

They note that the same equipment has been used for years to test blood from patients with other infectious diseases, such as HIV and hepatitis, and reused without problems.

"If this unfounded behavior continues, it could significantly impact the way hospitals care for these people," says Steven Hinrichs, chair of pathology and microbiology at the University of Nebraska and its affiliated

▶ STORY CONTINUES ON 2A