A four-year-old girl who had recently returned from West Africa arrived in the emergency room of a hospital in the northeastern United States.

She was suffering from a high fever and severe dehydration...
The largest commercial laboratory companies, all well-versed in handling specimens that contain dangerous pathogens, publicly announced they would not accept blood or tissue samples from Ebola patients.
Some indicated that their warranties called for “the [instrument] to be incinerated after its use for testing Ebola patients.”

Others explained that they would not have their technicians service equipment from isolation wards used for Ebola patients.
2014 Compass Group Survey

• College of American Pathologists (CAP) survey of the Compass Group, which includes 28 health care systems and more than 350 hospitals
  – Only 4 of 17 (24%) respondents would allow suspected or confirmed Ebola virus disease specimens into their laboratories
    • One of the four would restrict testing to a BSL3 laboratory
    • One of the four would discourage sending clinical specimens to the laboratory
Fear of Ebola Delayed Potential Life-Saving Treatments

• Complete blood counts, liver function tests, serum chemistries, and malaria tests were regularly deferred until there were assurances of a negative Ebola virus test result

• At least two persons who tested negative for Ebola died from other causes
Patient Care Suffered During the Ebola Crisis

Patient care vs. Safety concerns

Ebola
Biosafety Guidelines Vary Widely

- Inconsistencies in recommendations for handling infectious disease patients and their samples
- Code of Ethics of the American Society for Clinical Laboratory Science delineates duty to the patient, colleagues, and society
- Confusion about the nature of the virus led to a perception that Ebola represented an absolute risk

Alex Dubov, et al., 2016, “Ebola virus preparedness: emerging viruses and ethics in laboratory medicine,” Archives of Pathology and Laboratory Medicine, 140
Public Health Response Post-Ebola

• $21M over three years to enhance laboratory biosafety and biosecurity across the nation
  – Creation of full-time biosafety positions in 62 public health laboratory jurisdictions
  – Training and tools to support risk assessments, mitigation measures, and biosafety plans
  – Outreach to sentinel clinical laboratories
  – CDC/APHL Biosafety and Biosecurity Program
Clinical and Public Health Laboratories in the US

260,000 Laboratorizes in USA

Lab Personnel 800,000

CMS Quality Improvement Evaluation System
Limited Regulatory Environment

- Occupational Safety and Health Act (1970)
- OSHA final rule on occupational exposure to bloodborne pathogens (effective 1992)
- Clinical Laboratory Improvement Amendments (effective 1992)
Laboratory Exposures to *Brucella* in NYC, 2015-2017

- Samples from nine separate patients resulted in
  - 88 high-risk exposures
  - 101 low-risk exposures
  - 64 placed on prophylaxis
  - 187 under serological surveillance
- Procedures done on open bench during incidents
  - Venting blood cultures: 3/8 (38%)
  - Streaking of solid media: 4/8 (50%)
  - Catalase test: 3/8 (38%)
  - MALDI TOF MS preparation: 5/8 (63%)
  - Automated identification system sample prep: 4/8 (50%)
  - Median # days worked with isolate on bench: 2 (range 1-7)
Clinical Laboratory Biosafety is a Critical Unmet National Need

Learn more about the Division of Laboratory Systems initiatives to fulfill biosafety demand
Vision
Exemplary laboratory science and practice across clinical care and population health

Mission
Strengthen the nation’s clinical and public health laboratory system by continually improving quality and safety, informatics and data science, and workforce competency
Our Work

QUALITY AND SAFETY SYSTEMS

INFORMATICS AND DATA SCIENCE

TRAINING AND WORKFORCE DEVELOPMENT

PREPAREDNESS
Laboratory Safety

Laboratories are on the frontline of protecting everyone’s health. Laboratory safety sustains the wellness of local communities and the people who live, work, and play in them.

Safe laboratories enable trained staff to conduct accurate and timely tests and research, without jeopardizing the health of workers, the environment, or the public. By protecting laboratory staff and the public from biological, chemical, environmental, or physical hazards, CDC is leading the nation to strengthen a culture of laboratory safety.

CDC works around the clock to maintain safe laboratories in our agency and to help over 250,000 clinical and public health laboratories perform tests according to safety standards and best practices.

Resources

- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- Biosafety Initiatives in the Division of Laboratory Systems
- Competency Guidelines for Laboratory Professionals

CDC LABORATORY SAFETY

CLINICAL AND PUBLIC HEALTH LABORATORY SAFETY

www.cdc.gov/LabSafety
Clinical Laboratory Biosafety is a Critical Unmet National Need

Learn more about the Division of Laboratory Systems initiatives to fulfill a biosafety demand

www.cdc.gov/SafeLabs
DLS Initiatives in Laboratory Biosafety

• New chapter on clinical laboratory biosafety for the 6th Edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL)

• New guidance document “Decontamination of Laboratory Equipment and Instrumentation (QMS27)” to be developed by the Clinical and Laboratory Standards Institute (CLSI)
DLS Initiatives in Laboratory Biosafety

• Contributing to a new e-training module on laboratory risk assessment for the National Ebola Training and Education Center (NETEC)

• Collaborating with CDC SMEs and American Society for Microbiology (ASM) to revise guidance for clinical and microbiology teaching laboratories that work with *Salmonella* Typhimurium

• Developing a manuscript with many different collaborators to address the critical biosafety gaps identified during the Ebola outbreak and the challenges associated with clinical laboratory biosafety
Objective: Evaluate public health laboratory outreach efforts to sentinel clinical laboratories and conduct a clinical laboratory biosafety needs assessment

- Facilitate series of expert consultations on biosafety with public health and clinical laboratory professionals
- Supplement data collection on remaining gaps through a Biosafety in Clinical Laboratories Survey
- Collect and share successful models of public health laboratory outreach to sentinel clinical laboratories
Training and Workforce Development
Biosafety Cabinet Course

Fundamentals of Working Safely in a Biosafety Cabinet

CDC's NEWEST LABORATORY SAFETY COURSE

Centers for Disease Control and Prevention

www.cdc.gov/labtraining
Working Safely with Centrifuges

CDC’s NEWEST LABORATORY SAFETY COURSE

Centers for Disease Control and Prevention
Coming Soon!

New Chemical Fume Hood
Course Available

Centers for Disease Control and Prevention
Preparedness
Strengthening Communications

- Enhance emergency response communications with clinical laboratories through LOCS (LOCS@cdc.gov)
- Distributed 15 laboratory advisories, updates, and alerts to 24 clinical partner organizations, representing 190 countries and over 160,000 members since July 2017

- Connecting communicators to collaboratively raise awareness of clinical and public health laboratory resources and information
- Reaching membership from 18 partner organizations
- Launched website, distributed first newsletter, and held partnership call
National Challenges

• Absence of clear national regulations for clinical laboratory safety and biosafety
• Inconsistent and/or inadequate guidance
  – Agent-based approach to biosafety
  – Safety incidents basis for determining safety effectiveness
• Lack of preparedness for handling emerging infectious diseases and unusual outbreaks
Closing Comments

• With the end of three years of Ebola funding, there will no longer be a funded CDC program to advance laboratory biosafety across the United States

• Today the United States is more assertively advancing laboratory biosafety internationally than domestically
OUR STRENGTH IS IN ALL CAPS
Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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