Proficiency Testing for Infectious Disease Agents

Thomas L. Hearn, PhD
Associate Director for Laboratory Systems
Division of Public Health Partnerships
National Center for Health Marketing
Coordinating Center for Health Information and Service
Centers for Disease Control and Prevention

CLIA Advisory Committee Meeting
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Deadly Flu Strain Shipped Worldwide
Officials Race to Destroy Samples
By Rob Stein and Shankar Vedantam
Washington Post Staff Writers
Wednesday, April 13, 2005; Page A01

The New York Times ON THE WEB

NATIONAL DESK | April 13, 2005, Wednesday

Deadly 1957 Strain of Flu Is Found in Lab-Test Kits

Nearly 5,000 laboratories, mostly in the United States, were working Tuesday to destroy vials of a pandemic flu strain that were sent as part of a routine kit to test labs. ... The rush action, recommended by the World Health Organization of the United Nations, was prompted by a slim...

Stages of the H2N2 PT Event

- Identify laboratories receiving samples
- Notify laboratories and confirm that samples were destroyed

CDC's Role

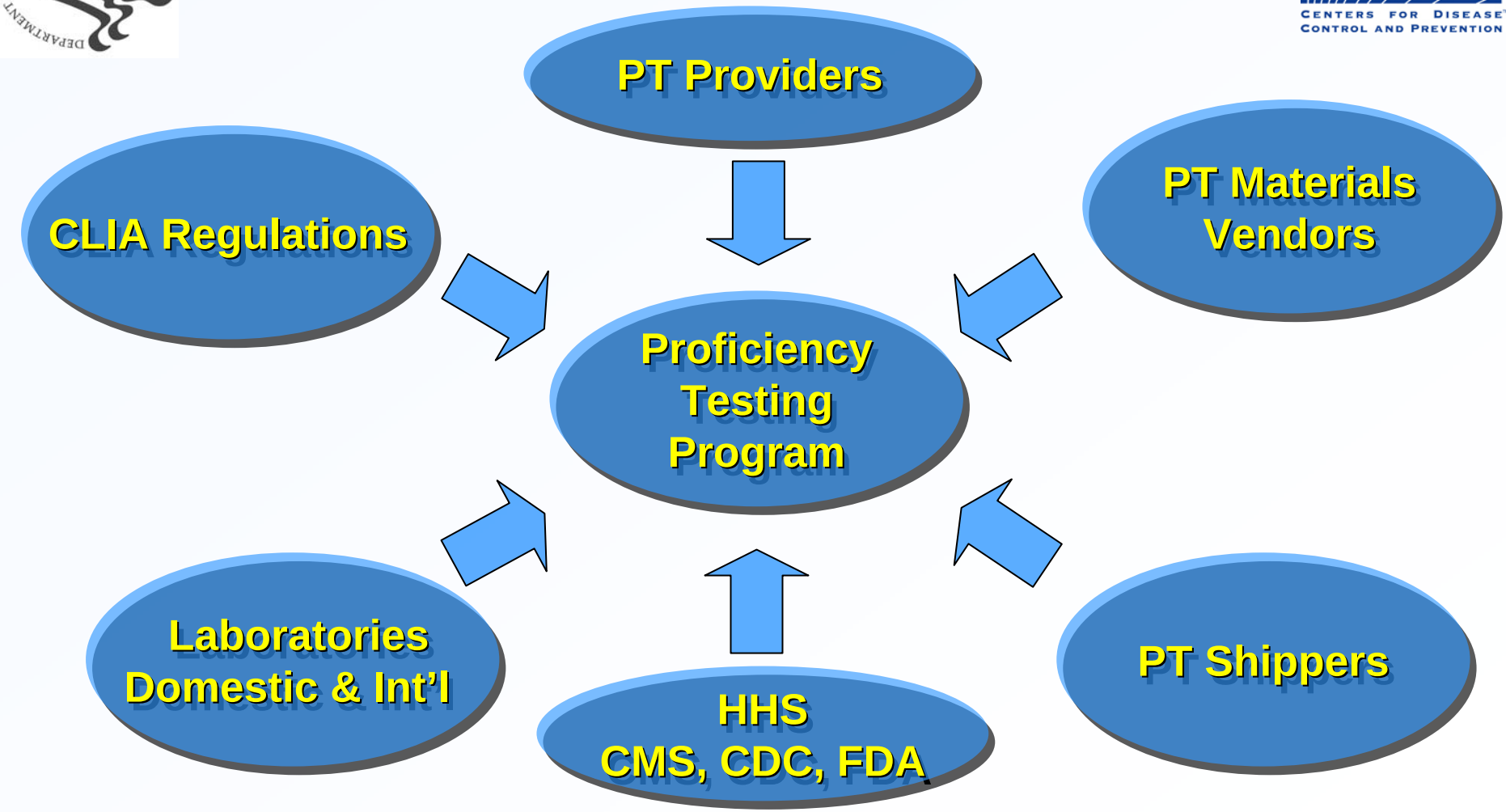
- Conduct Surveillance
- Investigate the root cause
- Implement measures to prevent similar reoccurrences

Action Items and Outcomes

- Designated a CDC Lead Team
  - Dan Jernigan, MD, MPH
  - Tom Hearn, PhD
  - Jan Nicholson, PhD
- Participated in HHS briefings: location and destruction of samples
- Investigated the root cause
- Convened PT experts and stakeholders
- Implementing recommendations

PT Experts and Stakeholders Meeting: June 14, 2005

- Engage stakeholders in issues of PT for infectious disease agents
- Share what happened in the case of H2N2 influenza PT (events and causal analysis)
- Discuss current regulations (CLIA, shipping and handling, BSL, etc)
- Discuss and get individual input about how to increase safety and reliability


PT Providers
CLIA Regulations
PT Materials Vendors
Proficiency Testing Program
Laboratories Domestic & Int'l
HHS CMS, CDC, FDA
PT Shippers

Agenda

- Introductions and opening remarks
- Proficiency testing requirements
  - ❖ CLIA
  - ❖ Other applicable regulations, including:
    - o Specimen shipping and handling
    - o Select Agent Rule
    - o Biosafety level requirements
- Events and causal factors: PT involving H2N2 influenza A
- Lessons learned and recommendations

Lessons Learned
...What Worked

- Laboratory community responsive
- In the more than 4000 laboratorians that received them, proficiency testing samples were...
  - handled,
  - tested, and
  - disposed of properly and safely
- Collaboration among stakeholders
- Communications
  - Frequent
  - CDC leadership

Lessons Learned
…What Worked Less Well

- Communications
  - International
  - PT materials vendors and PT providers (early on)
  - Public communications
- Data sharing
  - Lack of standards
  - No central database

Recommendations for What Worked Less Well

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Issues

- **Classification of H2N2 as a BSL2 agent**
- **Communication regarding epidemiologic significance**
- **CLIA regulations do not require CMS/CDC review of strain choices**

Recommendations

- H2N2 reclassified as a BSL3 agent
- CDC actively participate in review of organisms to be used by PT providers
- CLIA-approved PT programs should provide strain designations for PT samples and CDC should review strains

Issues

- **Live virus used for PT**
- **Lists of PT survey recipients were inadequate to allow immediate notification and determination of virus disposition**
- **Traceability of strains used to make PT samples**

Recommendations

- ❖ Use inactivated virus where technically reasonable
- ❖ Microbiology PT providers collaborating with CDC to enhance its data base for public health use
- ❖ Use good manufacturing practices to produce PT samples

Issues

- **Lack of specificity in manufacturing requirements**
- **ATCC policies and MTAs restricting transfer not considered**
- **International shipping regulations**

Recommendations

- ❖ PT providers provide more specificity
- ❖ Communication regarding importance of following policies
- ❖ PT provider verify information

Additional Recommendations

- Ship PT panels as UN3373, diagnostic specimens rather than UN2814 infectious substance
- Verify composition of PT sample contents before shipping
- PT providers and materials manufacturers should maintain materials safety data sheets so that in the event of a change in an organism's BSL or select agent classification, notice could be sent to those who had acquired the organisms

Additional Recommendations

- Provide easily accessible and up-to-date information on BSL and epidemiologic significance of organisms
- Have PT providers provide assurance to contractors that selected organisms are safe for domestic and international distribution
- PT materials suppliers conduct an annual internal reassessment of stock organisms maintained

Additional Recommendations

- Post a list of organisms recommended for use in PT
- Stored organisms must be clearly labeled and traceable to up-to-date information regarding pathogenicity, epidemiologic significance, and BSL
- Implement a process for “change orders” between PT providers and contractors

Additional Recommendations

- Communications with diagnostic device manufacturers to identify source of errors (laboratory performance, diagnostic device, or sample matrix) in PT events should be collaborative among the providers and their contractors, and made part of the record for the CLIA program's annual review
- PT providers should meet annually with their contractors

Additional Recommendations

- PT stakeholders meet annually with the CLIA program and public health agencies
- PT stakeholders should have a clear point of entry to public health
- Implement policies and procedures for emergency communications among all stakeholders
- Develop messages for public about safe and reliable practices of laboratories

Discussion

- Recommendations being implemented
- More discussion needed among stakeholders