Biosafety in Research and Clinical Settings

Jared N. Schwartz, MD, PhD, FCAP
CAP President

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“Biosafety is not just for the worker but also for the patient. We want to make sure the work environment is safe, while also ensuring both the patient and the public are safe.”

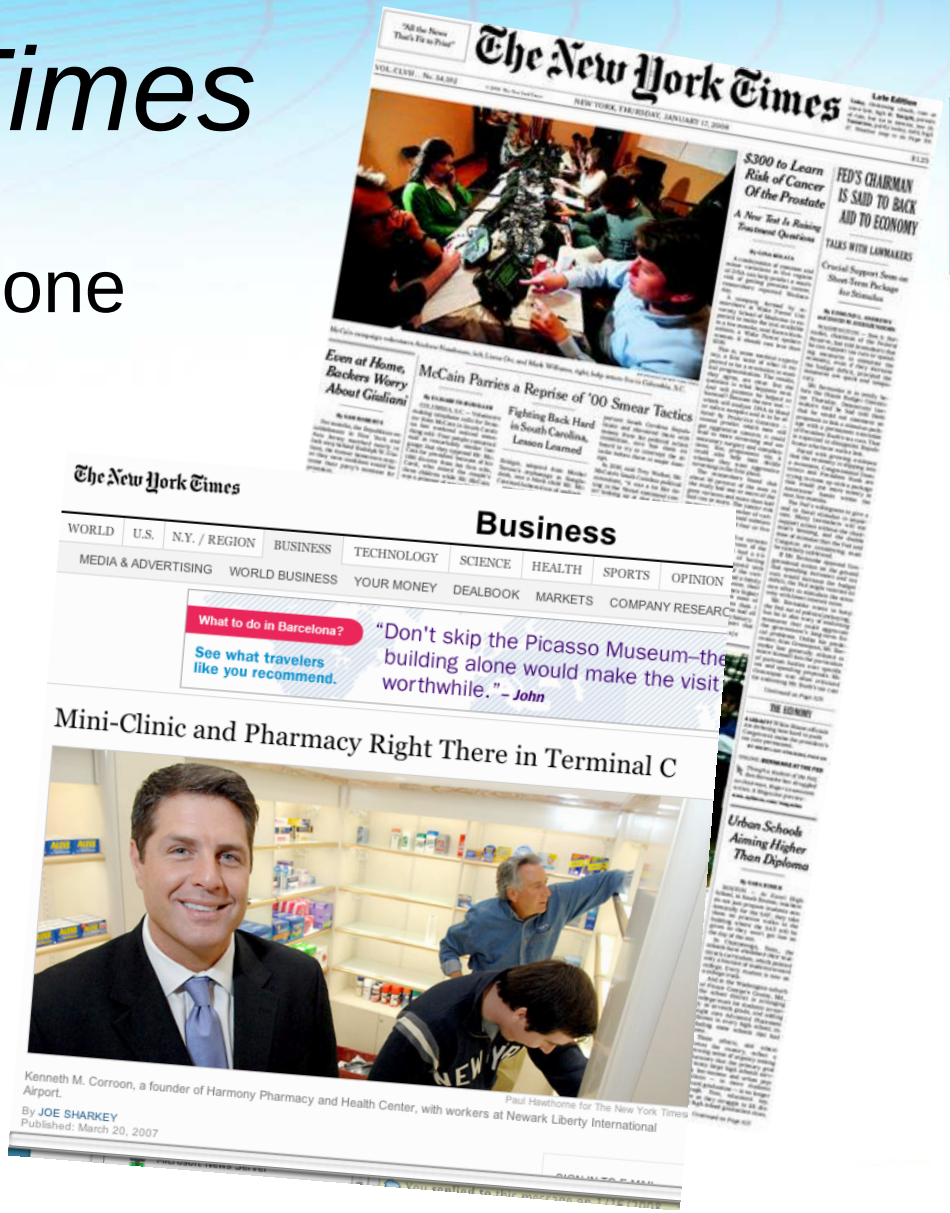
Jared N. Schwartz, MD, PhD, FCAP
CAP President

Biosafety:
Today's Clinical Setting

If you believe it is only the hospital microbiologist working behind the BSC—think again!

The New York Times

- Having a Little Work Done (at the Mall)
  - –Botox Treatment
  - –Laser Hair Removal
  - –Chemical Peels
  - –Wrinkle-filler Injections



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Biosafety:
Today's Clinical Setting

- POLs
- Mall health screens
- Health clubs
- Home
- Pharmacies
- Home health care
- Hospice
- Phlebotomy centers
- Nursing homes

How well do YOU understand safe work practices?

“ A phlebotomist who was observed not washing his hands between patients, was asked about his lab’s phlebotomy biosafety practices. The phlebotomist replied, ‘When we get a suspicious box, we immediately take it to Microbiology.’”

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How well do YOU understand engineering controls?

"A laboratory was cited for not having a BSL to process specimens for its Microbiology hood. In response to the citation, the lab purchased a chemical fume hood."

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Objectives

- Understand the variety and complexity of clinical settings
- Understand the challenges for maintaining a safe environment for workers and patients
- Understand the legal and societal expectations for a safe health care environment

Objectives

- Explain basic concepts of biological safety and applications in various work settings
- Explore methods for ensuring the integrity of samples
- Provide insights and tips for protection of coworkers, community members, and the environment

Patient Safety Goals

CMS-approved accreditation organizations have developed patient safety goals for clinical laboratory processes.

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FOR EXAMPLE
CAP Patient Safety Goal #1

- Improve patient and sample identification
  - Specimen collection
  - Analysis
  - Results delivery

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CAP Patient Safety Goal #2

- Improve the verification and communication of life-threatening or life-altering information regarding:
  - Malignancies
  - HIV and other infections
  - Cytogenetic abnormalities
  - Critical results

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CAP Patient Safety Goal #3

- Improve the identification, communication, and correction of errors

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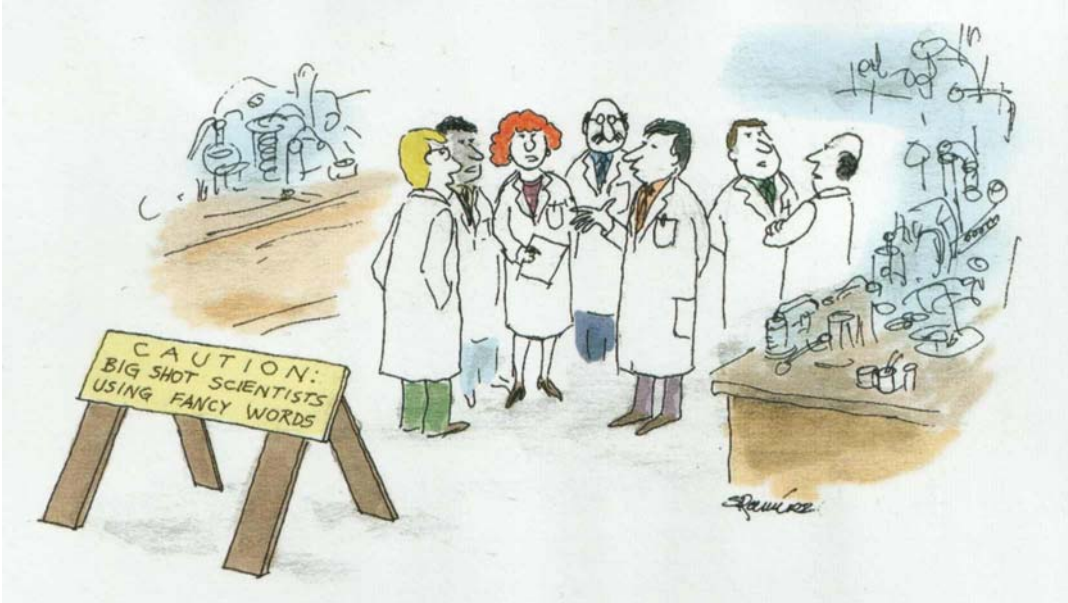
CAP Patient Safety Goal #4

- Improve coordination of the laboratory patient safety role within health care organizations (nursing, administration, POCT personnel, providers)



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Laboratory Accreditation Requirements for Patient Safety

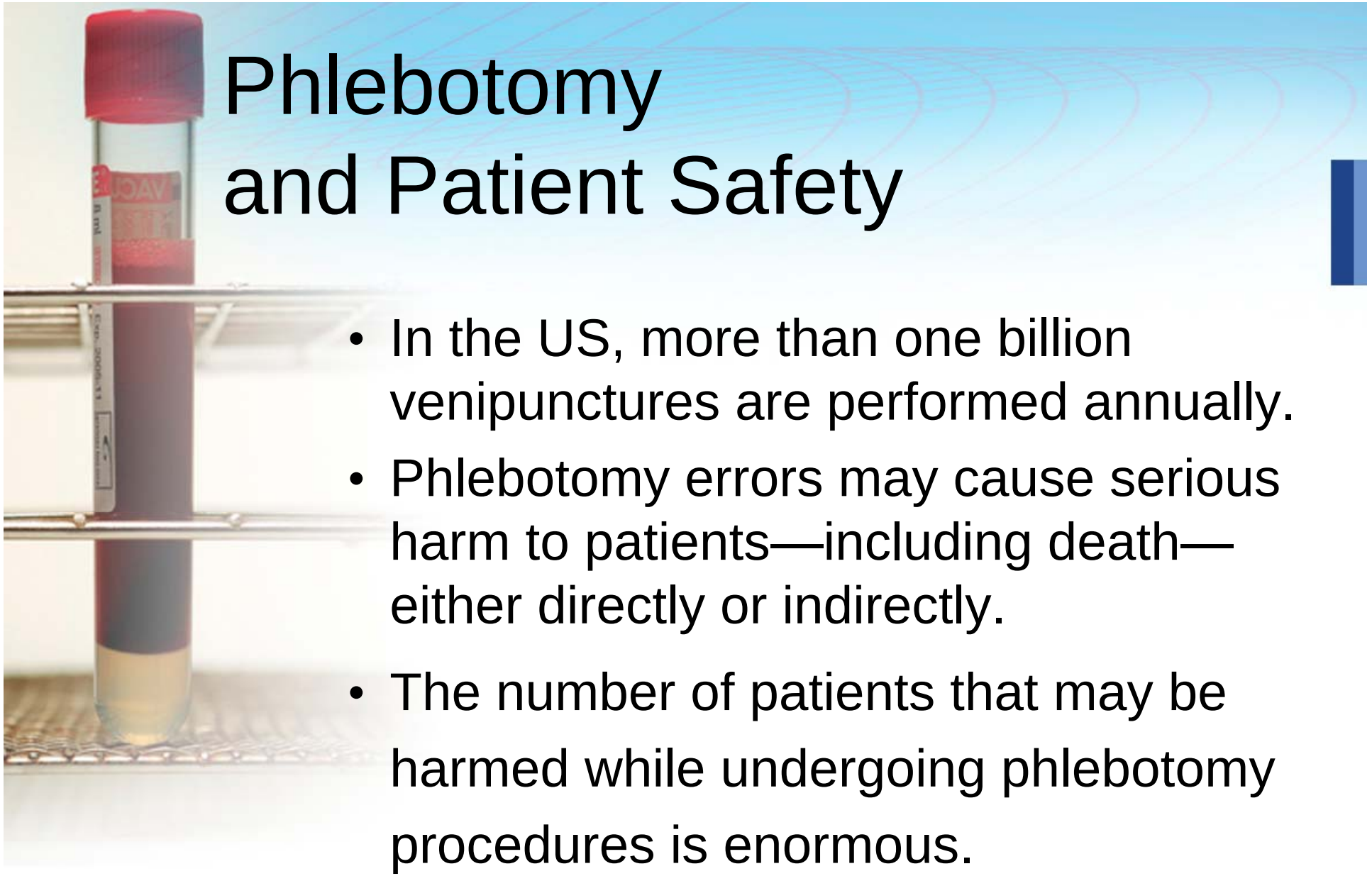
- Accreditation requirements contain multiple questions that deal with patient safety goals.
- Laboratories should emphasize these goals in their quality management activities.

Approaches

- Monitor activities as they relate to the goals (eg, number of mislabeled specimen containers)
- Take corrective/preventive action as necessary
- Investigate sentinel events with corrective/preventive action as necessary and evaluate and revise processes and procedures affecting the goals to optimize laboratory performance

Approaches

- Document how laboratory addresses patient safety goals
- Communicate inspection team findings that relate to patient safety goals to the laboratory director



Phlebotomy and Patient Safety

- In the US, more than one billion venipunctures are performed annually.
- Phlebotomy errors may cause serious harm to patients—including death—either directly or indirectly.
- The number of patients that may be harmed while undergoing phlebotomy procedures is enormous.

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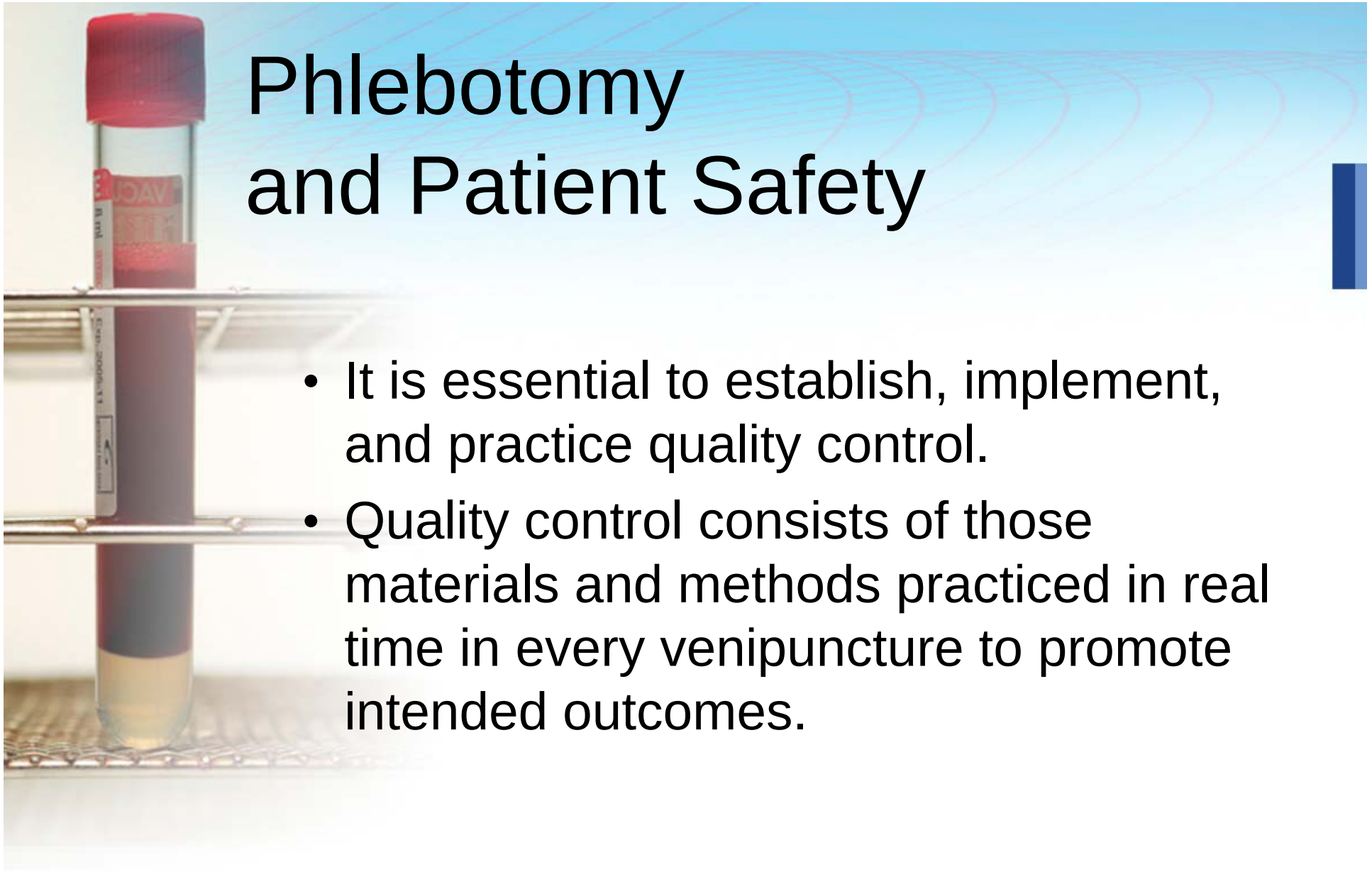
Phlebotomy and Patient Safety

- Before safety devices were introduced, phlebotomists reported an estimated 600,000 or more needlestick injuries annually. Therefore, the potential for harm to patients who are on the receiving end of every venipuncture is quite high.



Phlebotomy and Patient Safety

- It is essential to establish, implement, and practice quality control.
- Quality control consists of those materials and methods practiced in real time in every venipuncture to promote intended outcomes.

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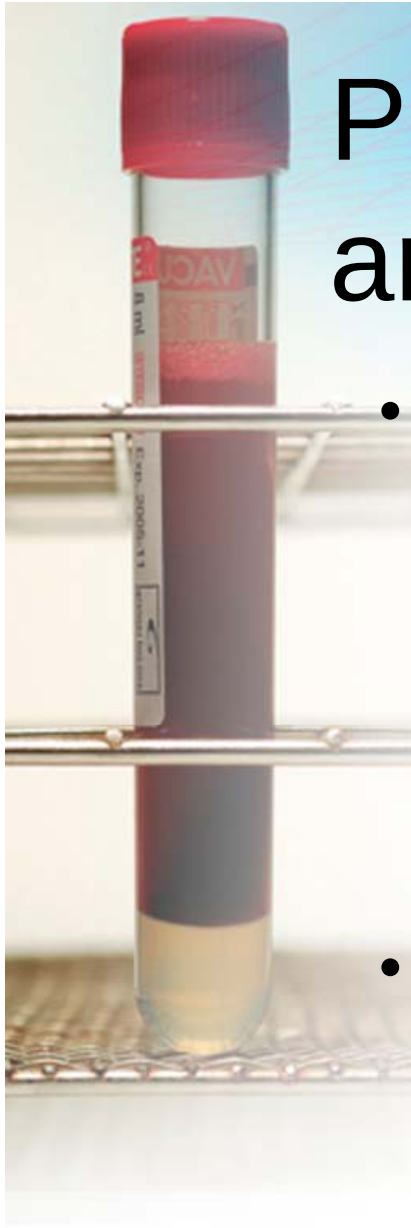
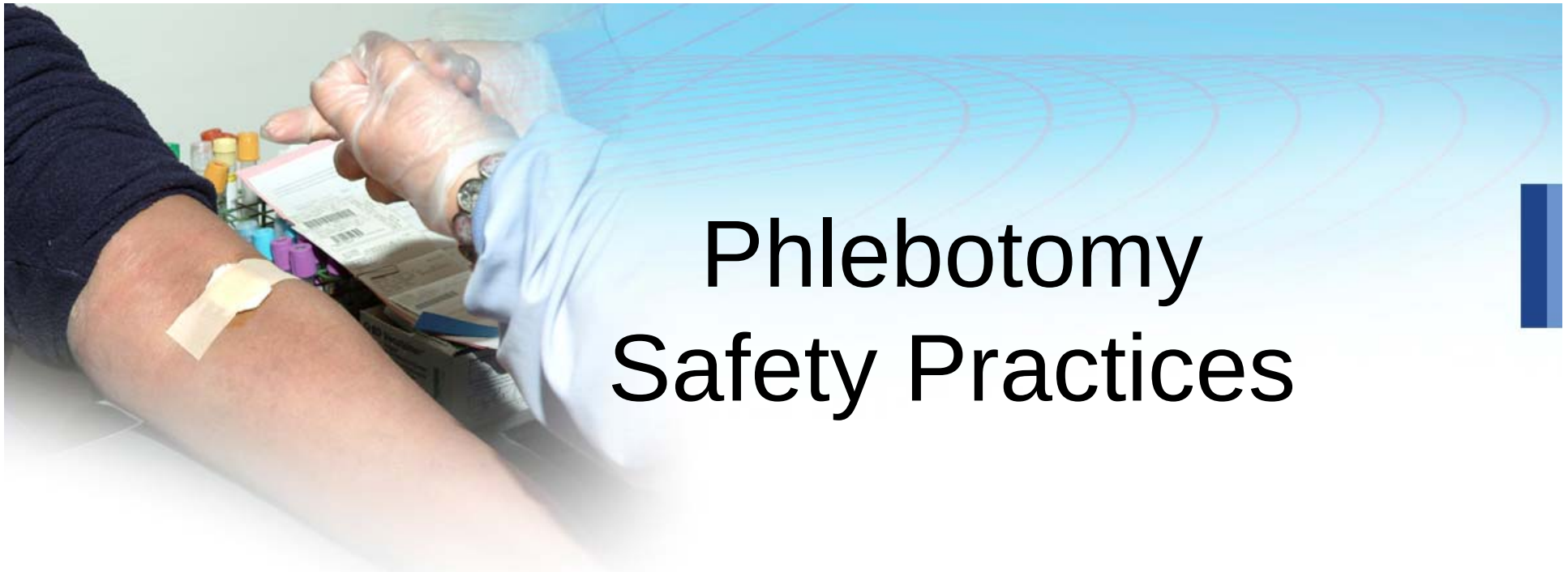


Phlebotomy and Patient Safety

- Phlebotomists enjoy the privilege of patient trust, as they are being permitted to perform an invasive procedure that no healthy individual would ordinarily volunteer to undergo.
- The dictum "*first, do no harm*" applies to phlebotomists as well as to physicians. Indeed, the etymology of "*safety*" is salvus, meaning "*freedom from harm*."



Phlebotomy Safety Practices

- Identifying the patient
- Communicating with the patient
- Choosing the "right stuff"

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Identifying the Patient

Phlebotomists need to know:

- The importance of accurately identifying their patients
- The possible outcome of failing to follow the protocol for identifying patients
- That failure to follow established identification protocol might lead to patient over-treatment or under-treatment
- The end result could be fatal if the patient has not been properly identified for blood bank/transfusion medicine testing

Communicating with the Patient

Communication—the means by which information is exchanged or transmitted between phlebotomist and the patient.

Involves three components:

- listening
- non-verbal
- verbal

Choosing the Right Stuff: Equipment Selection

- A phlebotomist must choose equipment appropriate to the vein used for venipuncture
- Failure to do this may result in harming patient

Phlebotomy and Patient Safety

- There are many opportunities for error in the phlebotomy arena
- Equally opportunities are available for learning and acquiring awareness to prevent errors
- Awareness equals prevention

Hand Washing

How long does it take to effectively wash your hands?

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Effective Hand Washing

- Maintains the cleanliness of environmental surfaces and infection control
- Recognized as one of the best means for preventing the spread of infections
- Minimizes the potential for infection to patients both directly or indirectly by hand contact
- Prevents health care personnel from becoming vectors of nosocomial pathogens

Hand Washing

- Improves adherence to safety and hygiene protocols
- Shown to terminate outbreaks in health care facilities
- Reduces overall infection rates
- Reduces transmission of antimicrobial resistant organisms (eg, MRSA)

The use of gloves does not eliminate the need for hand hygiene. Likewise, the use of hand hygiene does not eliminate the need for gloves.

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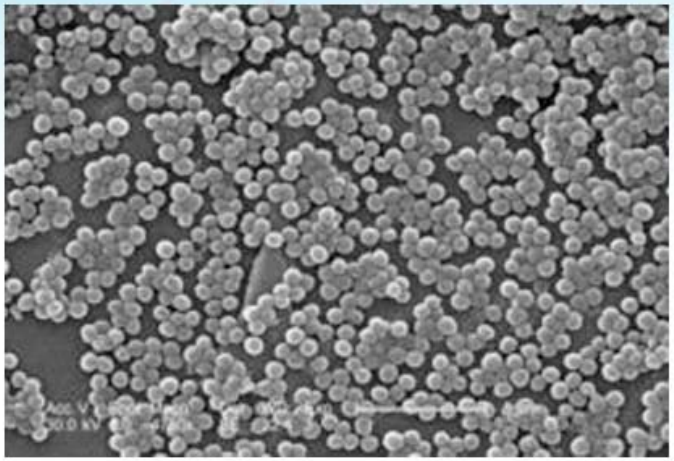
Hospital- and Community-Acquired Infections

The rise in the rate of hospital and community acquired infections caused by MRSA is alarming.

- The CAP, Centers for Disease Control and Prevention (CDC), and other public health officials are responding to the ever growing numbers of MRSA cases.

- State and federal legislators are passing laws requiring MRSA screening for all patients prior to hospital admission.

MRSA



MRSA

- More than 18 states now require hospitals to publish their infection rates.
- Many states have passed bills requiring hospitals to screen all intensive care and at-risk patients for MRSA.
- Nursing homes are beginning to screen residents for MRSA to combat the spread of this potentially deadly infection in the extended care environment.

MRSA

- The health care industry has responded to the need for a rapid turnaround time of detection results by developing screening tests for MRSA.

- Products now are available to provide screening results in as little as two hours—a significant improvement compared to culture methodologies requiring a minimum 24-hour incubation.

Laboratory Assessment Tool

- For example: The CAP, in conjunction with other organizations, has responded to this community need by offering a laboratory assessment tool for Methicillin Resistant *Staphylococcus aureus.*

- In response to the growing concerns about hospital-acquired MRSA infections.

Laboratory Assessment Tool

- Participants are challenged to assess proficiency in MRSA detection methods.
- This tool allows comparison of the effectiveness of available methods of detection.

Biosafety Risk Assessment (RA)

Risk assessment—a process used to identify:

- The hazardous characteristics of a known infectious or potentially infectious agent or material
- The activities that can result in a person's exposure to an agent
- The likelihood that such exposure will cause a laboratory associated infection (LAI)
- The probable consequences of such an infection

Factors to Consider in a Qualitative RA

- Risk assessment requires careful judgment.
- Adverse consequences are more likely to occur if the risks are underestimated.
- By contrast, imposition of safeguards which were more rigorous than needed can result in additional expense and burden for the laboratory.

"The issue is in deciding what is a reasonable precaution and what is bureaucratic overreaction."

Washington Winn, MD, FCAP
Microbiology Laboratory
Fletcher Allen Healthcare
Burlington, Vermont

Primary Factors to Consider

- Hazardous characteristics of agents
- Laboratory procedure hazards
- Staff capability to control hazards

  (This capability will depend on the training, technical proficiency, and good habits of all members of the laboratory staff.)

Strategies for Developing a Risk Assessment Review for Your Lab

- Identify agent hazards.
- Perform an initial assessment of risk.
- Identify laboratory procedure hazards.

Strategies for Developing a Risk Assessment Review for Your Lab

- Make a final determination of the appropriate biosafety level (BSL) requirements.
- Evaluate the competency of staff.

Who Is at the Heart of Biosafety?

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Personnel Competency Is Crucial

"The protection of laboratory workers, other institution personnel, and the public will depend largely on the laboratory workers themselves."

Source: Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington DC: Centers for Disease Control and Prevention and National Institutes of Health; 2007.

What Can YOU Do?

- EMPLOYEES — Follow safety protocols for handling infectious agents and be responsible when working with any known or potentially infectious agents or materials and associated equipment.

- SUPERVISORS — Ensure that all employees are trained and knowledgeable regarding safety procedures.

What Can YOU Do?

LABORATORY DIRECTORS —
Leadership is crucial to ensure:

- Technical competency by staff in the use of microbiological practices and safety equipment required for the safe handling of the agent
- Development of good habits by staff that sustain excellence in the performance of those practices
- An evaluation of personnel training, experience in handling infectious agents, competency in using sterile techniques and biological safety cabinets, ability to respond to emergencies, and willingness to be responsible for protecting surrounding employees and oneself

What Can YOU Do?

LABORATORY DIRECTORS MUST EVALUATE:

- Staffing levels
  - High workloads contribute to employee stress level
- Experience levels
  - Emphasis must be placed on competency and training of less experienced staff
- Employee fatigue
  - A strong relationship exists between fatigue and increased error rates
- Potential for worker safety issues

LABORATORY DIRECTOR LEADERSHIP

- Ensures that the physical plant and environmental conditions of the laboratory are appropriate for testing performed and provides a safe environment in which employees are protected from physical, chemical, and biological hazards
- Takes responsibility for providing the appropriate training of personnel

Tools Used to Assess Competency

- Directly observe patient testing and instrument operation
- Monitor test performance
- Record and report laboratory test results
- Foster problem-solving techniques and skills
- Retrain and reassess, if needed

Role of Biosafety Committee

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Role of Biosafety Committee

- Establish sound risk management practices and policies
- Oversee education and training
- Evaluate conditions through safety audits
- Review incidents (ie, safety complaints, “near misses,” accidents, facility failures)
- Implement changes to policies and procedures as needed
- Implement Needlestick and Sharp Injury Prevention Program

Biosafety Manual

Each lab must develop or adopt

a biosafety operations manual

- Identify any hazards that may be encountered
- Specify practices and procedures designed to minimize or eliminate exposures to these hazards
- Update to ensure manuals specific to the institution are current
- Include infection control, prevention, and practices
- Must match practices to procedures

Biosafety Levels

System for categorizing etiologic agents into groups

- Mode of Transmission
- Type and severity of illness
- Availability of treatment
- Availability of preventative measures

Biosafety Levels

- Developed in the 1970s
- Groupings were the basis for guidelines for appropriate facilities, containment equipment, procedure and work practices.
- Emerged into Biosafety Levels 1–4

Dr. Henry Fisher, pathologist, examines a specimen in the Pathology Lab, c.1890s.

Facility Design: Considerations

- Contributes to employee protection
- Provides a barrier to protect those outside of the laboratory

Facility Design:
Role of Laboratory Director

Lab directors are responsible for providing a safe work place ensuring the appropriate recommended biosafety level for the agents being manipulated.

- Lab space should be sufficient to minimize crowding, which may contribute to accidents.
- Lab surfaces, counters, and floors should be made of impervious materials to facilitate decontamination.

Your Compliance Toolbox

- The CAP Inspection Checklists have specific requirements to ensure laboratories meet CLIA ‘88 and CMS requirements
- Policies and procedures for the safe handling and processing of specimens and minimizing occupational risk of exposure should be kept close at hand for reading reference
- Engineering and work practice controls that are appropriate to the biosafety level of the lab should be maintained

The “Right Stuff” for Prevention

- Universal precautions
- Engineering controls
- Personal protective equipment (PPE)
- Safety Committee

Creating a ”Biosafety Culture" for Your Lab

- Develop a quality management plan that includes key indicators centered on safety
- Establish indicators with baseline and goals
- Create site-specific biosafety manuals
- Provide laboratory, supervisor and employee training
- Apply biosafety principles throughout the clinical laboratory
- Establish a safety committee
- Implement risk assessment

Care and Use of Your Biological Safety Cabinet (BSC)

- Biological Safety Cabinet is the primary containment device that protects workers and the work environment from exposure to microbiological agents.
- Persons who manipulate infectious organisms are at increased risk of acquiring an occupational illness if the BSC is not performing properly.

In the News….

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MMWR

Weekly

October 26, 2001 / 50(42);909-919

Update: Investigation of Bioterrorism-Related Anthrax and Interim Guidelines for Exposure Management and Antimicrobial Therapy, October 2001

Please note: An erratum has been published for this article. To view the erratum, please click here.

Since October 3, 2001, CDC and state and local public health authorities have been investigating cases of bioterrorism-related anthrax. This report updates previous findings, provides new information on case investigations in two additional areas, presents the susceptibility patterns of *Bacillus anthracis* isolates, and provides interim recommendations for managing potential threats and exposures and for treating anthrax.

Chicago Tribune

Sunday November 4, 2007

94,000 infections a year, many occurring outside of hospitals

How staph became drug-resistant threat

MRSA: Diligent hygiene is the key to preventing serious disease

MRSA: Diligent hygiene is the key to preventi

Illinois Department of Public Health

WEST NILE VIRUS

Rod R. Blagojevich, Governor • Damon T. Arnold, M.D., M.P.H., Director

West Nile Virus INFORMATION 866-369-9710

News Releases | Public Information | Health Care Provider Information | Surveillance 2007 2006 2005 2004 2003 2002 2001 U.S. 1999-2004 | Dead Bird Colecton

West Nile virus emerged in the United States in the New York metropolitan area in the fall of 1999. Since then, the virus, which can be transmitted to humans by the bite of an infected mosquito, has quickly spread across the country.

In Illinois, West Nile virus was first identified in September 2001 when laboratory tests confirmed its presence in two dead crows found in the Chicago area. The following year, the state's first human cases and deaths from West Nile disease were recorded and all but two of the state's 102 counties eventually reported a positive human, bird, mosquito or horse. By the end of 2002, Illinois had counted more human cases (884) and deaths (67) than any other state in the United States. In 2003, the epicenter of West Nile disease moved westward. Colorado reported the highest number of cases (2,947), easily surpassing the caseload record for the mosquito-borne disease set the previous year by Illinois. The number of West Nile human cases in Illinois fell dramatically with just 54 reported and only one death. Illinois' caseload in 2004 was slightly higher than the previous year with 60 reported cases and four deaths. In 2005, Illinois recorded 252 cases and 12 deaths, both totals the second highest in the nation to California's 880 cases and 19 deaths, and in 2006, there were 215 cases and 10 deaths reported, the sixth highest number of cases in the U.S.

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Auditing Your Program

What do inspectors look for when addressing biosafety concerns?

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Inspection Methods

Three methods of eliciting information during the inspection process:

- READ
- OBSERVE
- ASK

Inspection Methods

READ

—Review records and documents

Inspection Methods

OBSERVE

—Use direct observation

Inspection Methods

ASK

—Initiate follow-up questions for clarification

What would you do with that suspicious box?

Laboratory Preparedness

Policies and procedures exist for the recognition of isolates that may be used as agents of bioterrorism

Examples include (but are not limited to):

- *Bacillus anthracis* (anthrax)
- *Brucella* species (brucellosis)
- *Clostridium botulium* (botulism)
- *Francisella tularensis* (tularemia)
- *Yersinia pestis* (plague)
- *Variola* major (smallpox)

Laboratory Preparedness

- Laboratory Response Network
- Laboratory participation in the institution's bioterrorism response plan

Collaboration with the CDC

- More than 1,300 clinical laboratories throughout the US participate in the Laboratory Preparedness Exercise
- A collaborative effort involving the CAP, CDC, APHL, and ASM was initiated to improve the safety of our nation

MMWR Weekly

- Laboratories Did Not Follow Safety Procedure
  - Laboratory Preparedness Exercise
  - No One Injured
  - 250 Labs

CDC

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Weekly

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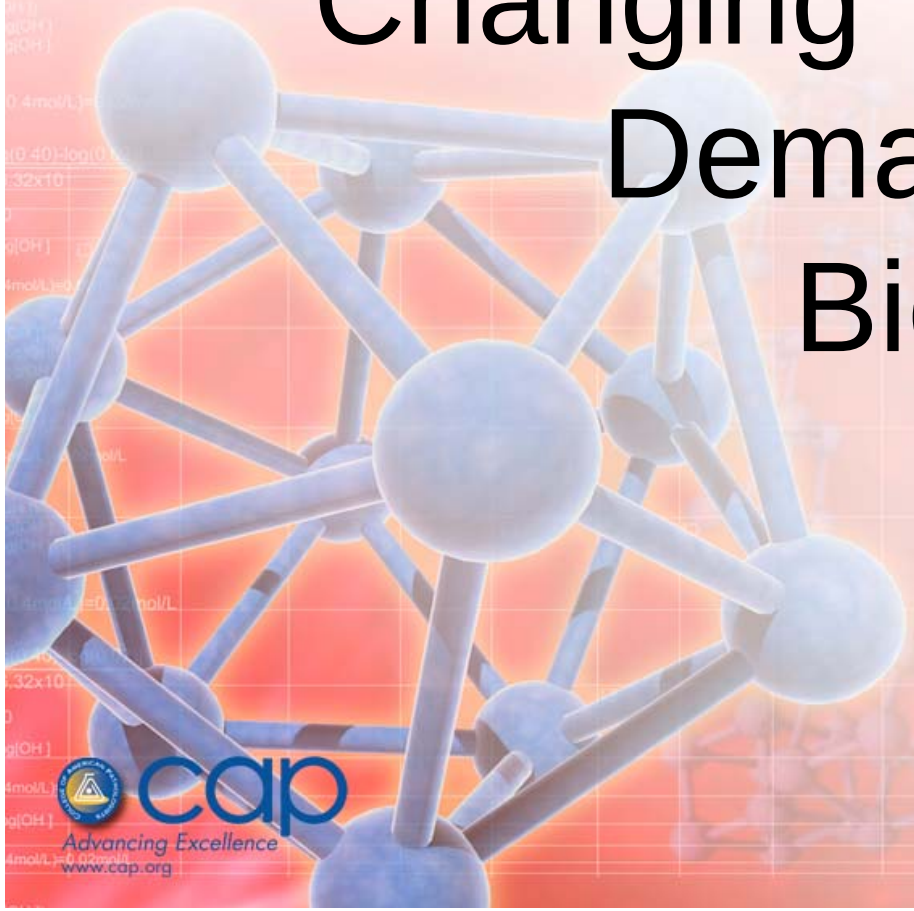
Laboratory Preparedness Exercise

- Tests the preparedness of laboratories across the United States to handle potential public health emergencies related to bioterrorism agents.
- Tests the response to communicate between sentinel laboratories and Laboratory Response Network reference laboratories
- Identifies gaps in emergency response systems

Changing Technology Demands Global Biosafety Mindset



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In Summary…

- Variable, expanded defintion for biosafety exists today
- Clinical care being delivered everywhere
- Risk assessment and education are key
- Director plays critical role in establishing biosafety culture
- Evaluate and adjust biosafety processes with rapidly changing environment