Medical Support for BSL-3 and -4 Labs at the NIH

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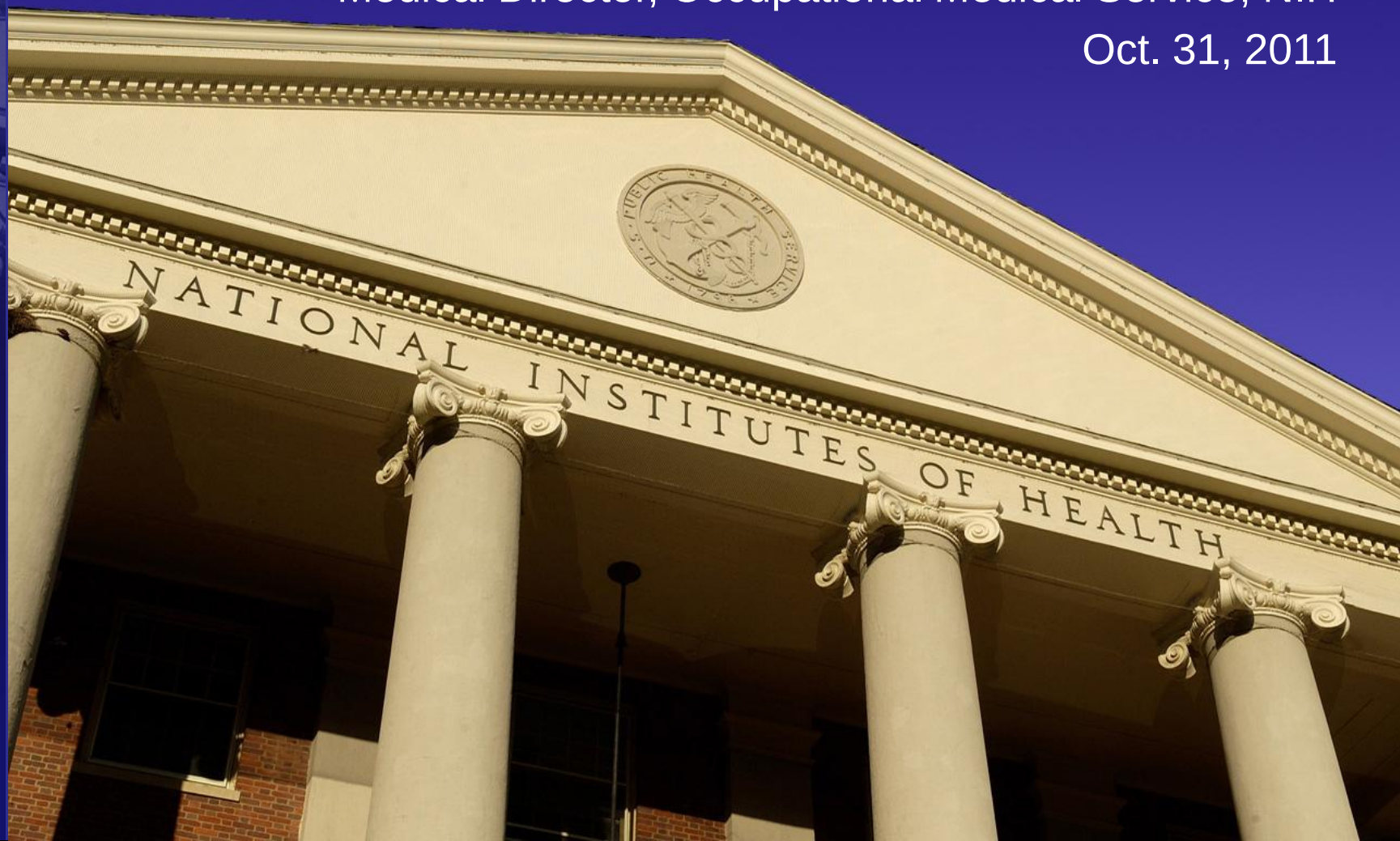

Recognition of OMS Staff

BSP coordinators

Karen Sova, CRNP

Gail Koffman, CRNP

Ms. Patricia Davis

On-site staff

Britton Townsend, RN

Jylla Artis, CRNP

Staff physician

Heike Bailin, MD

Nurse reviewers

Elsy Burnett-Schmitt, RN

Regina Jefferson, RN

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Mike Stockman, CRNP

Project manager

Jasmine Grams, MSW

Staff instructor

Mike Bray, MD

Presentation Outline

1. A brief introduction to the NIH and its Select Agent (SA) research
2. Overview of the NIH Biological Surety Program (BSP)
3. A detailed description of the occupational medical support for SA research performed at the NIH
    a. Enrollment medical evaluations
    b. Annual medical evaluations
    c. Event-driven medical evaluations
    d. Partnerships, training, and drills
4. Questions

The NIH SA Research

NIH SA research is focused on the development of vaccines, therapies, and diagnostic tests.

- The research is conducted in 2 ABSL-3, 26 BSL-3 and 10 BSL-4 labs.
- Laboratory locations:
  - Bethesda, MD (main campus) 20 BSL-3 and 2 ABSL-3 labs
  - Frederick, MD (30 mi away) 6 BSL-4 labs - pending
  - Hamilton, MT (2,300 mi away) 6 BSL-3 and 4 BSL-4 labs
- 347 workers are enrolled in the NIH BSP.
  - 253 workers are associated with BSL-3 labs
  - 94 work are associated with BSL-4 labs
- This represents slightly more than 1% of the NIH laboratories and badged workers.

Provisions of the NIH Biological Surety Program (BSP)

- Control measures to ensure that the workforce is:
  - Trained,
  - Responsible, and
  - Reliable, and
- Procedures to:
  - Protect employee health,
  - Ensure a safe work environment,
  - Preserve the integrity of the research,
  - Protect valuable research materials, and
  - Prevent loss or misuse of regulated biological materials.

Elements of the NIH BSP

1. Registration to work with Select Agents (SA)
   a. The NIH Institutional Biosafety Committee and
   b. The CDC Select Agent Program.
2. Security clearances
3. Occupational medical clearance
4. Training
   a. SA training
   b. BSL-3 or BSL-4 training (classroom and hands-on)
   c. Agent-specific training
5. Biosafety and operational manuals
6. Biological incident response procedures

Disclaimers

- What follows is a description of the current approach taken to provide medical support for workers conducting research with Select Agents at the NIH. It should not be interpreted as direction for steps any other organization should take to meet similar needs.
- This is not a static service. The details of this program are modified as needed to address changing administrative demands, incorporate evolving best medical practices, and provide the most efficient and effective service for NIH researchers.

Purpose

The goals of the medical support services are to:

- Assess medical and psychological fitness to work safely with or in the vicinity of SAs;
- Provide the worker with relevant health and safety information tailored to the relevant SA; and
- Offer immediate, expert medical support for potential occupational injuries and illnesses involving SAs.

The emphasis throughout is on prevention of occupational transmission and response preparation should an exposure or suspicious illness occur.

Eligibility

Participation in this program is required for federal and contract workers who have:

- Access to SAs,
- Unrestricted access to areas where SAs are stored, or
- Unrestricted access to critical infrastructure in "designated facilities"[1].

[1] = areas designed to accommodate the safe manipulation of SAs

Enrollment Process

1. The NIH Biosurety Manager (BSM):
   a. Identifies eligible workers,
   b. Directs them to the clinic,
   c. Provides the clinic with requisite information, so that the medical evaluation can be targeted to the worker's needs:
      - ✓ The type of lab,
      - ✓ the SAs (if any), and
      - ✓ Animals (if any) used in the research.

2. The clinic staff:
   a. Review the worker's clinical records to determine medical services indicated,
   b. Schedule necessary appointment(s), and
   c. Produce a weekly status report of evaluations in process.

Enrollment Process (cont.)

3. Overview of the enrollment medical evaluation:
   a. The complexity of the evaluation is tailored to the worker's needs (e.g., type of lab, SA involved, and animals contacted).
   b. There are 4 types of enrollment medical evaluations:
      i. BSL-3 general (no SA or animal contact),
      ii. BSL-3 agent-specific (SA and possible animal contact),
      iii. BSL-4 general (no SA contact)
      iv. BSL-4 cabinet/suit
   c. If SA use is planned, the exam is modified to include additional elements from the relevant agent-specific SOP.

Enrollment Process (cont.)

4. Agent-specific SOPs:
    a. Provide a summary of the organism(s)
        i. description of the organism,
        ii. routes and efficiency of transmission,
        iii. incubation period,
        iv. presenting symptoms, and
        v. diagnostic testing and treatment options.
    b. Outline agent-specific counseling and include related informational handouts.
    c. Identify supplies for the worker. Examples include: an agent-specific wallet card, a thermometer, surgical masks, a symptom log, and guidance on for minimizing transmission of the agent to others.

Enrollment Process (cont.)

5. List of NIH agent-specific SOPs:
   - Arenaviruses (Lassa, Junin, Machupo, et al.)
   - Bunyaviruses (RVFV and CCHFV)
   - Filoviruses (Ebola, Marburg)
   - Flaviviruses (TBEV, JEV, WNV, et al.)
   - Highly Pathogenic Influenza (HPAI, 1918, et al.)
   - Newcastle Disease Virus
   - Orthopox Viruses (Monkeypox, Cowpox, Camelpox)
   - SARS Coronavirus
   - *B. anthracis*
   - *B. mallei* and *pseudomallei*
   - MDR, TR *M. tuberculosis*

Enrollment Med Eval: BSL-3

The BSL-3 general and agent-specific[2] enrollment medical evaluations consist of:

1. Worker's description of duties (the history is compared to information provided by BSM).

2. Social history – personal use of alcohol and drugs, who lives at home and their health, and hobbies.

[2] = elements applicable to BSL-3 agent-specific, not BSL-3 general, evaluations are identified

Enrollment Med Eval: BSL-3 (cont.)

4. Vital signs (and only if clinically indicated, a targeted exam).
5. Enrollment in other relevant medical services – Animal Exposure Program, Allergy Program.
6. Immunizations (BSL-3 agent-specific).
7. Counseling:
   a. Must report all injuries and febrile illnesses;
   b. First aid measures are discussed in detail;
   c. The SA – transmission, incubation; earliest presenting symptoms (BSL-3 agent-specific), and
   d. Activating the emergency medical response system.
8. Provision of supplies – wallet card. Supplies listed above in agent-specific SOPs (BSL-3 agent-specific).

Enrollment Med Eval: BSL-4

The BSL-4 general and cabinet/suit[3] enrollment medical evaluations consist of:

1. All the elements of the BSL-3 general enrollment medical evaluation.
2. Additional counseling and supplies, as provided in the BSL-3 agent-specific evaluation.
3. Behavioral health screening and face-to-face meeting with a psychologist . Workers are screened for:
   a. Anxiety,
   b. Depression, and
   c. Likely adherence to safety rules.

[3] = elements applicable to BSL-4 cabinet/suit, not BSL-4 general, evaluations

Enrollment Med Eval: BSL-4 (cont.)

4. Baseline hearing test (BSL-4 cabinet/suit).
5. Visual acuity testing – near, distant, color, and depth (BSL-4 cabinet/suit).
6. Lipid panel for a 10-year cardiac risk assessment using the Framingham Heart Study (BSL-4 cabinet/suit). Individuals with a 10% or greater risk of a cardiovascular event with the next 10 years are referred to an appropriate healthcare provider for further cardiac evaluation.

Annual Medical Evaluations

The BSM directs all enrollees to return for medical evaluation each year. The evaluations include:

1. Worker's description of duties and work-injuries in past year.

2. Medical history, including:
   a. Febrile illnesses in the past year,
   b. A review of organ systems,
   c. Newly diagnosed medical conditions,
   d. Changes in medications taken, and
   e. Hospitalizations and surgeries in the past year.

3. Social history – personal use of alcohol and drugs, who lives at home and their health, and hobbies.

Annual Medical Evaluations (cont.)

4. Behavioral health screening for BSL-4 general and cabinet/suit workers.
5. 10-year cardiac risk assessment for BSL-4 cabinet/suit workers whose value was not less than 2.5% in the preceding 3 years.
6. Repeat serum sample every 3 years.
7. Review and update of immunizations, as occupationally indicated.
8. Review of counseling and supplies provided at last evaluation. (Quiz the worker on the advice given at prior evaluations.)

Potentially Disqualifying Information (PDI)

The Certifying Medical Authority determines whether a worker is medically qualified to enroll or remain in the program.

1. Medical conditions are disqualifying, if they can be expected to result in:
    a. An altered state of consciousness,
    b. Impaired judgment or concentration,
    c. Increased risk of serious injury if exposed to biologic hazards,
    d. Impaired ability to use required PPE, or
    e. Inability to perform the physical requirements of the position.

PDI (cont.)

2. Examples of PDI that may result in immediate disqualification include:
   a. Attempt to conceal PDI,
   b. Current diagnosis of drug or alcohol dependence,
   c. Drug trafficking within 15 years,
   d. Drug abuse while enrolled in the BSP,
   e. Inability to meet safety requirements.

3. Examples of PDI that may prompt further medical evaluation include:
   a. Failure to fully disclose PDI,
   b. A history of suicide attempts or threats,
   c. Medical conditions that may impair the worker's level of consciousness, concentration, or judgment,
   d. Cardiac risk estimate greater than 10%.

Event-Driven Med Evals

Potential exposures to a SA or an unexplained fevers prompt emergency medical evaluations.

1. There is a well-defined process that utilizes the agent-specific procedures and infectious disease (ID) and subject matter expert (SME) consultants.
2. Medical care is available 24/7.
3. The occupational medical physician coordinates the medical response. He or she:
   a. Obtains a detailed description of the circumstances from the worker and, if relevant, from the PI and safety specialist.
   b. Carefully evaluates the wound and provides appropriate care.

Event-Driven Med Evals (cont.)

c. Obtains and stores an acute serum sample.
d. Consults several knowledgeable ID and SME consultants, as needed.
e. Estimates the risk of transmission from the consultants' assessments.
f. Decides on limitations for the worker's activities, diagnostic testing, and treatment plans, using advice provided by consultants.

4. If there is <u>any</u> concern that a laboratory-acquired infection may have occurred, the occupational medical physician:
   a. Discusses the concern with the worker, provides advice, and keeps the worker informed while arranging for transportation and further evaluation.

Event-Driven Med Evals (cont.)

b. Notifies:
    i. PI,
    ii. BSP Certifying Official,
    iii. Emergency transport services,
    iv. Hospital administrator, and
    v. Laboratory.
c. Requests transfer by emergency transport services, once notified that the hospital is prepared to receive the worker.
d. Discharges clinical responsibility for the worker to the the hospital ID specialist when the worker is received by the emergency transport service.

Event-Driven Med Evals (cont.)

5. Follow-up
   a. The occurrence and each step of the response is reviewed, as soon as possible, following the event.
   b. Every effort is made to identify areas for possible improvement in the process.
   c. The occupational medical physician remains involved in the care of the worker. Obtains a convalescent serum sample at an appropriate point following the initial report of injury or illness for all cases, regardless of whether the worker is transferred to the direct care of the ID specialist.

Relationships, Staff Training and Drills

Given the infrequency of these events, it is imperative that staff have an understanding of SAs and their respective roles in responding to potential occupational exposures or illnesses involving a SA.

1. Develop and foster relationships with PIs, research staff, safety specialists, infectious disease consultants, subject matter experts, emergency response personnel, hospital personnel, public health officials, and communications officer.
2. Maintain readiness by providing ongoing training and drills, and reviewing and revising relevant procedures.

Staff Training: Presentations

07/29/10	Laboratory acquired infections
08/05/10	Poxviral infections
09/02/10	Influenza: H2N2 seasonal, H5N1 avian, H1N1 1918
10/07/10	SARS
11/04/10	Hendra and Nipah virus
12/09/10	Ebola and Marburg hemorrhagic fever
01/06/11	Lassa and Rift Valley fever, Crimean-Congo hem fever
02/03/11	South American arenaviruses
02/10/11	Principles of Immunization
03/03/11	Hantavirus pulmonary syndrome
03/24/11	Filoviruses Demystified
04/14/11	West Nile virus
05/26/11	Equine encephalitis viruses
06/09/11	Herpes B virus
08/04/11	Tick-borne encephalitis and Omsk hemorrhagic fever
10/13/11	Anthrax and Tularemia

Staff Training: Drills

07/23/08	Bethesda	Tabletop exercise 6 scenarios, all parties represented
02/26/09	RML	BSL-4 Extraction drill – unconscious worker
11/04/09	RML	BSL-4 Extraction drill – unconscious worker
03/24/10	RML	BSL-4 Emergency response – injured worker
08/25/10	RML	BSL-4 Transport drill – ill worker
03/22/11	RML	BSL-3 Extraction drill – unconscious worker
04/07/11	RML	BSL-4 Transport drill – ill worker returning from the Congo
05/11/11	USAMRIID	BSL-4 Transport drill – injured worker
08/04/11	IRF Fred.	BSL-4 Transport drill – injured worker
09/28/11	NBACC	BSL-4 Emergency response – injured worker

Questions?