Medical Support for Biomedical Research

James M Schmitt, MD, MS
Medical Director, Occupational Medical Service, NIH
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Overview

1. Relevant guidelines
2. Medical support – basics
3. The NIH as a customer
4. Medical support services at NIH
   - The Animal Exposure Program
   - Allergies
   - Work related injuries
   - Biological Surety Program
Guidelines and Regulations

- OH&S in the Care and Use of Research Animals (NRC 1997)
- OH&S in the Care and Use of Nonhuman Primates (NRC 2003)
- Guide for the Care and Use of Laboratory Animals 8th Ed, (NRC 2011)
- Biosafety in Microbiological and Biomedical Laboratories 5th Ed, 2009
- Americans with Disabilities Act of 1990
- Americans with Disabilities Act Amendments Act of 2008
- OSHA regulations (29 CFR, Part 1910)
Medical Support Services: the Basics
Purpose

To promote a safe and healthy workplace through the provision of work-related medical services

Recognition

This is one more support service. It must:

• balance management needs and employee rights, while

• routinely demonstrating respect for those we seek to serve.
Alternative Approaches for Medical Support

Occupational Medicine (OM)

- Medical services designed to meet work-related needs, may include emergency medical care and health promotion.
- Focused, a challenge to keep current.

Employee Health (EH)

- More expansive, less tailored.
- Includes a wider range of non-emergent personal healthcare services.
Prevention

- **Primary** – avoid the injury (by removing the hazard, utilizing barriers, training)
- **Secondary** – early detection and treatment of an injury
- **Tertiary** – minimizing long-term consequences of an injury
Where does this group fit in the organization?

- Environmental Health and Safety (EHS)
- Student Health
- Facilities (if responsible for EHS)
- Human Resources
- Contracted (on- and off-site)

Regardless, the service needs to be readily accessible to employees.
Essential Partners

- Occupational safety and health specialists
- Investigators, subject matter experts
- Veterinary resources
- Human resources
- Other support services (facility mgmt)
- Employees
- Senior management - support
Understanding the Environment

- Interaction with partners
- A description of the workplace
  - Identified health hazards
  - Animals used in research
- Relevant literature
- Committees
  - Institutional Biosafety Committee
  - Institutional Animal Care and Use Committee
  - IC Safety and Health Committees
What Is “Medical Surveillance”? 

Careful monitoring to detect early clinical evidence of injury and permit early treatment, and to prevent further injury.

• Medical support services for biomedical research rarely meet this definition.

• The timely evaluation of occupational injuries and appropriate sharing of selected, related information is perhaps our most effective option.

The speaker’s opinion
Medical Surveillance Requirements

1. A test that is:

- Reliable,
- Acceptable,
- Sensitive (few ‘false negatives’),
- Specific (few ‘false positives’), and
- Capable of detecting an injury in time to make a difference.
2. A plan for the systematic collection and analysis of data.

3. An understanding of the prevalence of the finding in the community is essential for a meaningful analysis of the data.

4. A strategy for communicating the results of the analysis in a timely fashion with those that need to know.
Medical Surveillance Requirements (cont.)

- The “Guide” (p.22-23) states:
  - “Periodic medical evaluations are advisable for personnel in specific risk categories. For example, personnel required to use respiratory protection…”
  - “the medical surveillance program should promote the early diagnosis of allergies…”
  - “Zoonoses surveillance should be part of an occupational health and safety program.” Those with nonhuman primate contact “should be routinely screened for tuberculosis.”

- Only screening for TB meets the definition for “medical surveillance”
Confidentiality of Medical Information

- OM as public health in a workplace.
  - Dual responsibility to the employee (patient) and employer (public).
- Must protect the confidentiality of the employee's medical information, while providing necessary information to the employer to assist in the maintenance of a safe workplace.
Medical Evaluations and Services

- Preplacement medical evaluations
- Routine, periodic medical evaluations
- For-cause medical evaluations
  - Occupational injuries and illnesses
  - Incapacity – personal injury or illness and intoxication
- Serum storage
Preplacement Medical Evaluation

- A rote baseline physical exam does not offer sufficient value to recommend it.

- An opportunity to:
  - Discuss personal medical and immunization history,
  - Review workplace health hazards,
  - Describe first aid and emergency medical care,
  - Provide work-related immunizations, and
  - Offer relevant counseling.
Routine, Periodic Medical Evaluations

- In general, routine medical evaluations are not warranted.
  - Work with BSL-3 and -4 agents and toxins are an exception to that general statement.
For-Cause Medical Evaluations

- All suspected occupational injuries and illnesses **must** be reported.
  - OSHA General Duty Clause
  - OSHA 300 log
  - Workers’ Compensation

- Personal injuries and illnesses that compromise a worker’s ability to perform occupational duties safely warrant appropriate medical evaluation.
Serum Storage

- Routine storage of serum is rarely useful.
  - Work with BSL-3 and -4 agents and toxins *may* constitute an exception to that assertion.

- Serum stored at the time of report of a potential exposure to a biologic hazard (acute specimen) and 6-8 weeks following the incident (convalescent specimen) have proven clinically useful.
The NIH as a Customer
The NIH

- The world’s largest biomedical research facility.

- Its mission:
  - To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illnesses and disability.

- How it is organized:
  - 27 Institutes and Centers (ICs) each with its own specific research agenda.
The NIH (cont.)

- Annual budget: $31.2 B
  - Extramural program – more than 80% is awarded via competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools and other research institutions.
  - Intramural program – 10% supports NIH researchers. Approximately $1.2 B spent on animal research activities by 24 ICs.

- Locations
  - MD (Bethesda, Poolesville, Frederick, Baltimore), MT, NC, and field stations
The NIH (cont.)

- The workforce
  - 18,700 badged federal employees
  - 18,300 badged contractors and visitors
  - An average of 22,000 workers on the main campus any given day
  - More than 20% hold at least one doctoral degree
  - Approximately 20% are foreign born
  - Approximately 10-20% turnover per year
The NIH (cont.)

- Research animals – 1.7 M used in 2010
  - 83% Mice
  - 3.5% Rats
  - 13.5% Fish and frogs
  - 0.3% Guinea pigs, rabbits, and hamsters
  - 0.3% Nonhuman primates

- Over 125 human pathogens studied

- More than 2,500 research laboratories
  - Approximately 25 BSL-3 and 8 BSL-4
Medical Support at NIH
Medical Support at NIH

- **Approach:** OM (rather than EH) design, implement, and reassess services intended to address occupational health concerns of the NIH community.

- **Organization:** a component of the Division of Occupational Health and Safety.

- **Eligibility:** principally for federal workers
  - Contractors receive: care for medical emergencies and work injuries, unique services (e.g., anthrax vaccine, Biological Surety Program), and flu shots.
Medical Support at NIH (cont.)

- **Staffing:**
  - MDs (2), Allergist (.1), PAs/NPs (4), RNs (8), PT (.5), Lab tech (1), EAP counselors (3), Workers’ Comp specialist (1).

- **Locations:**
  - MD (Bethesda, Frederick, Baltimore), MT.

- **Hours:**
  - 7:30-5:00, 24/7 on-call for life-threatening injuries and illnesses

- **Computer support – customized**
Medical Support at NIH (cont.)

- **Animal Exposure Program (AEP, no “S”)**
  - Eligibility: federal workers with access to research animals or their living quarters
  - Participation and compliance are mandatory (mandatory minimum requirements for compliance are defined)
  - Subdivided by type of animal contacted (small, large, nonhuman primate [NHP], and viable NHP tissue)
  - Enrollment and compliance reported online and in real time
Medical Support at NIH (cont.)

- Medical elements of the AEP provided for all participants on enrollment:
  - Review of position responsibilities and medical and immunization history,
  - Tdap booster dose, if warranted,
  - Other occupationally-indicated immunizations, and
  - **Counseling**: allergies, zoonoses, agent/toxin-specific, requirement to report all work injuries, first aid, and accessing emergency care for occupational injuries
Medical Support at NIH (cont.)

- Additional medical elements of the AEP
  - Large animal: occupationally indicated testing (ex: toxoplasmosis antibody testing for women of child bearing capacity)
  - NHP: rubeola screening and immunization (if clinically warranted), enrollment in the TB Surveillance Program, wallet cards
  - NHP tissues: offered voluntary enrollment in the TB Surveillance Program

- Recall: only for AEP participants with access to NHPs without evidence of prior infection with *mTB*; annual testing
Medical Support at NIH (cont.)

- Other relevant medical services
  - Work-related allergy clinic
  - Care for work-related injuries
  - Biological Surety Program

- Allergies: no surveillance
  - Rely on counseling, training, and self reporting
  - Allergy testing and care provided onsite
Medical Support at NIH (cont.)

- Care for work-related injuries
  - All injuries must be reported
  - All reported to safety for investigation
  - Provide complete care for more than 80% of work-related injuries sustained by federal workers and all injuries involving potential exposure exotic or highly pathogenic agents.
  - Consult as needed with SMEs and infectious disease specialists
  - Plan and drill for incidents involving BSL-3 and -4 agents
Medical Support at NIH (cont.)

- Biological Surety Program (BSP)
  - Eligibility: federal and contract workers with access to select agents and toxins in designated facilities (DF) or unrestricted access to the critical infrastructure of a DF
  - Participation and compliance is mandatory
  - Design: layered services similar to AEP (BSL-3, agent-specific, BSL-4)
  - We have gent-specific procedures for select agents and toxins studied
  - Annual drills involving: labs, H&S, transport, medical, and hospital services
Questions?