

Medical Support for Biomedical Research

James M Schmitt, MD, MS

Medical Director, Occupational Medical Service, NIH

Sept. 8, 2011



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.



Medical Surveillance Requirements (cont.)

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 on-line 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 agent-specific procedures for select agents and toxins studied
 - Annual drills involving: labs, H&S, transport, medical, and hospital services

Questions?

