Occupational Health Services at the Food and Drug Administration

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Overview

• US Food and Drug Administration
• Occupational Health Services
  – Work-Related Medical Support
  – Surveillance Programs
  – Wellness Programs
• Planning a Surveillance Program
• Summary
What does FDA do?
What does FDA do?

- Protect the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protect the public from electronic product radiation
- Assure cosmetics and dietary supplements are safe and properly labeled
- Regulate tobacco products
- Advance the public health by helping to speed product innovations
- FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions
Who Works for FDA?
Who Works for FDA?

- Researchers – microbiologists, chemists, biologists, pharmacologists
- Medical officers – medical doctors, veterinarians, nurses, laboratory technicians, pharmacists
- Research support – animal caretakers, other specialized research technicians
- Professional and administrative – executive, administrative, budget officers; attorneys; information technology specialists; engineers; consumer safety officers; investigators; statisticians; clerical staff
- Technical and trades workers – utility engineers, carpenters, electricians, machine shop workers
Where is FDA
FDA in the National Capital Region
White Oak Campus

Silver Spring, MD
Thirteen (13) field testing labs across the US

Additional Center for Food Safety and Applied Nutrition (CFSAN) labs (2)
Over 200 ORA field offices across the US and overseas
Occupational Health Services

Sustaining a healthy workplace for FDA employees by providing occupational health services, counseling, and training as well as by ensuring compliance with regulatory requirements and guidelines in occupational safety and health.
FDA’s Clinical Support

• 5 Clinics in the National Capital Region
• Network of Clinics Across the Country
  – Through an Inter-Agency agreement
• Plan to Extend Support Overseas
  – Currently FDA employees may see their primary care provider for work-related health support if no FDA contract facility can be reached.

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Occupational Health Services
Occupational Health Services

Work-Related Medical Support

• Fitness for Duty Evaluations
  – Preplacement
  – Return to work
  – Job performance

• Medical Clearance for Respirator Use

• Medical Support for International Travel
  – Clearance
  – Counseling
  – Vaccinations

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Occupational Health Services

Work-Related Medical Support

- Work-Related Immunizations
- Occupational Injury and Illness Evaluations
  - Wound Care
  - Medications
  - Referrals
Occupational Health Services
Surveillance Programs

• For Employees with Potential Worksite Exposure to Specific Hazards
  – Animal Exposure Program
  – Select Agent Program
  – Zika Virus Program
Occupational Health Services

Wellness Programs

• October Flu Vaccination Campaign
• Disease Management
  – Diabetes
  – High blood pressure
• Health Fairs

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Occupational Health Services
Planning a Surveillance Program

1) Describe
2) Enroll
3) Monitor
4) Evaluate
5) Respond
6) Communicate
7) Coordinate
8) Review
Why Plan?
Planning a Surveillance Program

• Step 1: Understand the Pathogen/Toxin
  – Use reliable resources
    • Safety Data Sheets
    • Biosafety in Microbiological Laboratories – 5th Edition
    • Occupational Safety and Health Administration/National Institute for Occupational Safety and Health
    • Centers for Disease Control and Prevention
    • Public Health Agency of Canada (http://www.phac-aspc.gc.ca/id-mi/az-index-eng.php#ai)
Planning a Surveillance Program

• Step 2: Determine Enrollment
  – Who needs surveillance?
    • Everyone?
    • Specific job title?
    • Specific job duty?
    • Specific location?
Planning a Surveillance Program

• Step 3: Determine health impacts and methods of exposure monitoring
  – What health issues can influence safe and/or effective work with the pathogen/toxin?
  – What test(s) need to be performed?
  – Be mindful of ADA regulations!!
Planning a Surveillance Program

• Step 4: Determine How Often to Evaluate
  – For cause vs. periodic
Planning a Surveillance Program

• Step 5: Determine Post-exposure Evaluation Procedures
  – OSHA standards
  – BMBL recommendations
  – Is there an antidote/medication
  – Pertinent testing
  – Work status
Planning a Surveillance Program

• Step 6: Prepare Hazard Communication Resources
  – Tell employees why surveillance is necessary.
Planning a Surveillance Program

• Step 7: Coordination Between Occupational Health and Safety
  – Standardize communications
  – Develop records management protocols
Planning a Surveillance Program

• Step 8: Periodic review of program
  – Keep up to date with current science
Planning a Surveillance Program

Example: ZIKA VIRUS

• Step 1: Resources
  – BMBL
  – OSHA/NIOSH
  – Public Health Agency of Canada
  – CDC

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Planning a Surveillance Program

Example: ZIKA VIRUS

• Step 2: Enrollment Criteria
  – Zika lab access
  – Traveling to epidemic areas
Planning a Surveillance Program

Example: ZIKA VIRUS

• Step 3: Pertinent Health Conditions
  – Pregnancy!!
  – Considering pregnancy
  – Vaccination status (flu vaccine)

• Exposure Monitoring
  – Questionnaire
  – Labs (as per current CDC recommendations)
1) Have you or your significant other visited any of the following areas in the last six (6) months? (If none, proceed to question 3)
   a. South America
   b. Pacific Islands
   c. Central America
   d. Caribbean
   e. Cape Verde
   f. Mexico
   g. US Virgin Islands or Puerto Rico
   h. Southeast Asia
   i. NONE

2) During your travel or within 2 weeks or return did you or your significant other have:
   a. Fever
   b. Rash
   c. Muscle and Joint aches
   d. Conjunctivitis/pink eye

3) Have you ever been diagnosed with Dengue Fever?

4) Are you or your spouse pregnant or planning to become pregnant within the next 2 years?
Planning a Surveillance Program

Example: ZIKA VIRUS

• Step 4: Periodicity of Evaluations
  – Before lab access is granted
  – Before travel
  – Annually for BSL-3 labs
Planning a Surveillance Program

Example: ZIKA VIRUS

• Step 5: Post-Exposure/Illness Evaluation
  – Wound care/personal health history review
  – Baseline testing for anti-flaviviral IgG antibodies
    • Per CDC recommendations
  – Temperature/symptoms log for 10 days
  – Consider infectious disease consult and repeat bloodwork after 6 weeks
Planning a Surveillance Program

Example: ZIKA VIRUS

- Step 6: Hazard Communication
  - Risks of infection
  - Transmission
  - Symptoms
  - Prevention
  - Post-exposure procedures
Planning a Surveillance Program

FDA FACT SHEET

ZIKA VIRUS INFORMATION FOR FDA EMPLOYEES

This fact sheet provides information on Zika virus and Zika disease for FDA employees who may potentially be exposed during the performance of normal job duties.

Virus Information
Zika virus is a mosquito-borne flavivirus, transmitted primarily by the Aedes aegypti mosquito. Aedes mosquitoes have a wide and expanding global distribution, including the United States. These are the same mosquitoes that spread dengue, chikungunya, and yellow fever viruses.

Areas where Zika Virus is active
Prior to 2015, Zika virus outbreaks have occurred in areas of Africa, Southeast Asia, and the Pacific Islands. In May 2015, the first local transmission of Zika virus infection (Zika) was reported in South America. Local transmission means that mosquitoes in the area have been infected with Zika virus, spreading it to people. Currently, outbreaks are occurring in many countries including:

<table>
<thead>
<tr>
<th>Caribbean</th>
<th>Central America</th>
<th>The Pacific Islands</th>
<th>South America</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anguilla; Antigua and Barbuda; Aruba; The Bahamas; Barbados; Bonaire; British Virgin Islands; Cayman Islands; Cuba; Curacao; Dominica; Dominican Republic; Grenada; Guadeloupe; Haiti; Jamaica; Martinique; Montserrat; the Commonwealth of Puerto Rico, a US Territory; Sabot; Saint Barthelemy; Saint Kitts and Nevis; Saint Lucia; Saint Martin; Saint Vincent and the Grenadines; Sint Eustatius; Sint Maarten; Trinidad and Tobago; Turks and Caicos Islands; US Virgin Islands.</td>
<td>Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama</td>
<td>Fiji, Marshall Islands, Micronesia, Palau, Pagoa New Guinea, Samoa, Solomon Islands, Tonga</td>
<td>Argentina, Bolivia, Brazil, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Suriname, Venezuela</td>
<td>Cape Verde, Angola, Guinea-Bissau, Mexico, Maldives, Singapore</td>
</tr>
</tbody>
</table>

It is notable that Zika is endemic in some countries in Africa, the Pacific Islands, and Asia. This means Zika cases have been reported in the past and occasional new cases may be reported. The risk of transmission to travelers is lower in endemic areas, so these countries do not have travel notices posted and are not listed above. It should be noted that CDC recommends pregnant women consult with their healthcare provider prior to travel to the following countries in Southeast Asia, Africa, Asia, and the Pacific Islands: Brunei, Burma (Myanmar), Cambodia, Indonesia, Laos, Malaysia, Maldives, Philippines, Thailand, Timor-Leste (East Timor), Vietnam, Angola, Benin, Burkina-Faso, Cameroon, Central African Republic, Côte d’Ivoire, Egypt, Ethiopia, Gabon, Guinea-Bissau, Kenya, Liberia, Mali, Mozambique, Niger, Nigeria, Senegal, Sierra Leone, Somalia, Tanzania, Togo, Uganda, Zambia, Bangladesh, India, Pakistan, Easter Island, and Vanuatu.

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Planning a Surveillance Program

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Zika Virus Counseling Record

Name | Date
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I have received counseling about:

- how I may be exposed to Zika virus during travel or in the laboratory;
- the risks of infection with Zika virus, including the potential for birth defects in the fetus; and
- how to protect myself from exposure to Zika virus during travel or in the laboratory, including covering exposed skin, using EPA-registered insect repellents, and using standard precautions, certain types of personal protective equipment, and specific lab practices/procedures.

In addition:

- I have discussed my Zika virus-related health concerns with the OHS clinician or my health care provider, and my questions were answered to my satisfaction.

As a result of the information I have received, I am able to make an informed decision as to whether or not I will accept the risk of being exposed to Zika virus.

I decide to (Select one):

- [ ] accept the risks of Zika virus transmission associated with travel or other FDA duties, or
- [ ] decline FDA duties and travel that may increase risk of Zika transmission.

Employee Acknowledgement, and Concurrence of Clinician/Provider and Supervisor

<table>
<thead>
<tr>
<th>Employee Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>OHS Clinician or Healthcare Provider Signature</td>
<td>Date</td>
</tr>
<tr>
<td>Supervisor Signature</td>
<td>Date</td>
</tr>
</tbody>
</table>
Planning a Surveillance Program

Example: ZIKA VIRUS

• Step 7: Coordinate Communications
  – Incident report
  – Emergency resources list
Planning a Surveillance Program

Step 8: Example: ZIKA VIRUS

• Program Review
  – Triennially
  – Occupational Health Services
  – Safety Office
Summary

• US Food and Drug Administration
  – Expansive mission, diverse employee population, multiple widespread locations

• Occupational Health Services
  – Work-related health care

• Planning a Surveillance Program
  – Protect employees through readiness and prevention
Questions??