National Institute for Occupational Safety and Health

Health Hazard Evaluation Program

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Presentation Overview

- Introduction to NIOSH
- What is a health hazard evaluation (HHE)?
- Regulatory authority
- What happens during an HHE?
- HHE reports
- Case studies from the HHE Program
- How to request an HHE
Differences: OSHA and NIOSH

OSHA: Occupational Safety and Health Administration
DOL: Department of Labor / DHHS: Department of Health and Human Services

NIOSH

- Conducts scientific research
- Develops guidance and authoritative recommendations
- Disseminates information
- Responds to requests for workplace health hazard evaluations
Health Hazard Evaluation (HHE)

• An HHE is a study of a workplace to determine whether workers are exposed to harmful substances, agents, or conditions
• Requestors contact NIOSH for this free service
• Facility-specific recommendations are made to control identified hazards

Who in NIOSH Performs Health Hazard Evaluations and Provides Technical Assistance?

Personnel include*
  – Industrial Hygienists
  – Medical Officers (Physicians, Veterinarian, Nurse)
  – Technicians
  – Epidemiologist
  – Behavioral Scientist
  – Statistician
  – Health Communication Specialist
  – Other specialists as needed from around NIOSH (Engineers, Health Physicists, etc.)

*Staff from the NIOSH Division of Surveillance, Hazard Evaluations and Field Studies, Hazard Evaluations and Technical Assistance Branch; and Division of Respiratory Disease Studies
Regulatory Authority

Title 42, CFR, Part 85 allows NIOSH:

• Right of entry
• To access pertinent records maintained by the employer or third parties
• To conduct private and confidential employee interviews
• Request space for confidential interviews and exams
• To require employee representation at meetings and the walk-through survey
• Act on conditions of imminent danger

Valid HHE Requestors

• Employer Requestor
• Union Requestor
  • An authorized representative of the employees for collective bargaining purposes
• Employee Requestor(s)
  • Current employee who is authorized, in writing, by at least two other current employees to represent them
  • One of three or fewer current employees

We also provide technical assistance to local, state, and federal agencies, upon request.
Who Requests HHEs?

- Employee: 54%
- Government: 11%
- Management: 20%
- Other: 13%
- Union: 2%

2006-2010

During the HHE

- Employee requestors can remain confidential
- Participation in the HHE is voluntary
- Collected personal information is confidential
- Interviews and exams are conducted in private
- Requestors and participants are protected by the OSHA whistleblower protection from discrimination and retaliatory acts
When an HHE Can Help

- New hazards, exposures, processes, or controls
- Illnesses from an unknown cause
- Exposure to unregulated agents or hazards
- Adverse health effects at exposures less than current standards
- Emergency response situations

New Exposures, Processes, or Hazards: Carbon Monoxide (CO) Exposure from Houseboats

- In 2000, 2 brothers died swimming near their family houseboat
- HHE Program received several requests to evaluate CO exposures from houseboat generators - concern for employees working on or around houseboats
- 176 acute boat-related poisonings, with 14 deaths identified from 1990 – 2004
- CO concentrations up to 30,000 ppm were found in the airspace under the rear swim platform
- Results led to changes to exhaust stack designs and new exhaust emission controls
Illness of Unknown Cause: 
Respiratory Symptoms at an Indoor Water Park

Patrons and Workers reported upper respiratory symptoms, asthma

We compared life guard’s symptoms to an unexposed group and assessed chloramine and endotoxin levels in air

Results showed that on days when more patrons were in the pool and on colder days when ventilation was shut down or reduced, chloramines levels were higher, and symptom prevalences were higher

Unknown Scope of Exposures in Workers: 
Marine Mammal Site

Workers and volunteers rescue and study sick and dead marine mammals and conduct autopsies

We are evaluating work practices and potential exposures
Serosurvey:
- Leptospirosis
- Q fever
- Brucellosis
Old Problems in New Places:
Silica exposures from Roofing Tile Construction in the Southwest

• Sawing through cement roofing tiles generated respirable silica dust, exceeding occupational exposure limits
• Lack of respiratory protection, limited training, no medical surveillance, language barriers, transient workforce contributed to problems
• Lung function testing found decrements in lung function related to years worked in roofing tile industry

Emerging Issue:
Keratin Based Hair Straighteners

• Hair salons using straightening products containing or releasing formaldehyde
• Employee exposures exceeded occupational exposure limits for formaldehyde
• The Brazilian Blowout Acai Professional Smoothing Solution – Formaldehyde Free Smoothing Formula contained 11% formaldehyde by weight
• We recommended discontinuing use of this product or implementing controls and requirements in the OSHA formaldehyde standard
Response Without a Site Visit

- Utilized when:
  - Well known problems
  - Recognized solutions
  - Available guidance

- Response includes:
  - Referrals
  - Phone consults
  - Letters of information/recommendations

Response With a Site Visit

May Include...

- Observation of procedures and work practices
- Discussion with workers, supervisors, managers, and union reps
- Review of exposure records, OSHA logs, and health records
- Collection of environmental and biological samples
- Confidential medical interviews and exams
- Evaluation of controls
HHE Reports

- **Sent to:**
  - Employee representatives
  - Employer
  - OSHA
  - Health dept.

- **Available through:**
  - Epi-X
  - NIOSH eNews
  - NIOSH web site

Impact of HHEs

**At Worksites:**
- Identify hazards
- Document exposures and health effects
- Provide recommendations

**On Science:**
- Sampling and analytic methods
- Epidemiologic studies
- Engineering controls

**On Policy and Regulation:**
- Assess existing standards
- Support new standards
Other Activities and Initiatives

- Green jobs initiative
- Hispanic worker outreach
- Followback program
- Emergency response

Case Studies
Campylobacter Infection and Exposures Among Employees at a Poultry Processing Plant

Project Officers:
LCDR Marie A. de Perio, MD
CAPT John D. Gibbins, DVM, MPH
R. Todd Niemeier, MS, CIH

Full Report:

HHE Request

• In 2008, investigation and recommendations by VA Dept. of Health (VDH) for campylobacter infections
• VDH referred plant to HHE program after more cases of campylobacteriosis identified
• Plant management submitted HHE request in 2011 regarding Campylobacter infection
• Specific concern about employees in live hang area
Background on *Campylobacter* Infection

- Also known as campylobacteriosis
- Common cause of gastrointestinal (GI) infection
- Most often associated with sporadic cases of illness
- Symptoms:
  - Diarrhea (may be bloody)
  - Cramping, abdominal pain
  - Fever
  - Nausea and vomiting

Background on *Campylobacter* Infection

- Transmission occurs through:
  - Consumption of undercooked poultry
  - Handling of raw poultry
- Commensal organism of poultry
- Can be found on skin, feathers, GI tract
Poultry Processing Plant

• Processed 300,000–350,000 birds/day
• 1,000 employees over three shifts
• Agreement with Virginia Dept. of Corrections to provide 16 week work assignments for 24–35 diversion center residents at any time

HHE Objectives

• Estimate incidence of acute GI illness among plant employees
• Investigate incidence of *Campylobacter* infection among plant employees from 2009–2011
• Assess controls in place to reduce Campylobacter contamination
HHE Methods

- Visited plant May, 2011
- Reviewed encounter records from plant medical office
- Observed of work practices
- Observed of plant’s ventilation system
- Reviewed carcass sampling program for Campylobacter
- Reviewed laboratory-diagnosed Campylobacter cases among plant employees

Plant Medical Office Records

- Reviewed encounter records from January 2010–September 2011
- Tabulated GI-related encounters by month
- GI-related encounters
  - In 2010, 273 (16%) of 1,716 encounters
  - In 2011 (through Sept.), 221 (15%) of 1,543 encounters
Observation of Work Practices

• Two water coolers in live hang area
• Live hang employees left line briefly to drink water without removing PPE
• A potential source of exposure

Observation of Work Practices

• Inconsistent hand washing across many areas of plant especially after removing PPE
• Most soap dispensers and waste receptacles not hands free
Observation of Work Practices

- Inconsistent and suboptimal use and removal of PPE
- Live hang employees
  - Smocks in break room
  - No safety glasses
  - N95 respirators worn incorrectly
- Some employees not required to wear gloves
  - Liver/gizzard inspectors
  - Drawers/venters in evisceration
  - Rehang

Review of Laboratory Diagnosed Cases

- 29 cases from January 2008 – May 2011
- Median age: 29 years, range: 19–52 years
- 29 males, 1 female
- 26 (90%) resided at one of two diversion centers
- 24 (83%) worked at plant for < 1 month before illness onset
- Work location of cases:
  - Live hang (n = 18)
  - Evisceration (n = 8)
  - Other (n = 3)
- *Other includes kill room, rehang, cut-up
Review of Laboratory Diagnosed Cases

- Obtained records for 24 cases
- Symptoms:
  - Diarrhea (n = 24)
  - Abdominal cramping (n = 14)
  - Fever (n = 9)
  - Headache (n = 7)
  - Nausea and vomiting (n = 6)
  - Muscle aches (n = 3)
- 17 treated with antibiotics
- 1 hospitalization, no deaths

Review of Plant Ventilation System

- Designed to move air in direction opposite process flow (clean → dirty)
- Live hang area renovated in 2010
- HVAC system provided 100% outdoor air in live hang area
- Supply air from ducts located above employees’ heads is directed toward conveyor holding chickens to be shackled
Review of Environmental Sampling Programs

• USDA/FSIS requires microbial testing, sanitation standard operating procedures
• From December 21, 2010–April 20, 2011, 6 (1.4%) carcass samples positive for *Campylobacter*
• Within performance standard guidelines

* USDA/FSIS: U.S. Department of Agriculture/Food Safety and Inspection Service

Discussion

• 29 laboratory-diagnosed *Campylobacter* cases over 3½ year period
• Most occurred in employees in live hang
  – Area of known high contamination
  – Airflow of ventilation system in area may aerosolize potential contamination
  – Water coolers present possible source of exposure
  – Observed suboptimal hand washing and PPE use
Discussion

• Most cases occurred in new diversion center employees
  – Suggests protective immunity in longer term employees
  – May be partially attributed to better access to health care than permanent employees
• Almost 500 GI-related illness encounters in plant medical office in < 2 years, which appears high
• Likely underestimation of true incidence of infection and illness due to underreporting

Recommendations: Engineering Controls

• Install hands-free soap dispensers and waste receptacles
• Move water coolers in live hang area to outside
• Sanitize and dry transport cages
• Modify supply vents in live hang area to redirect airflow
• Wet down birds before shackling
Recommendations: Administrative Controls

• Improve training and compliance of employees on hand hygiene
• Train plant medical staff to recognize and inquire about diarrheal illness
• Re-examine plant’s sick leave policy to ensure employees do not work when ill

Recommendations: PPE

• Provide training to employees on proper use of PPE
• Provide PPE at no cost to employees
• Encourage compliance with PPE requirements
• Consider making use of face shields mandatory in live hang area
Pharmaceutical dust exposures at a mail order pharmacy

Project Officer: Kenneth W. Fent, PhD
Industrial Hygienist, NIOSH


Health Hazard Evaluation (HHE) Request

• Mail order pharmacy managers requested an HHE
  – Concerning potential employee exposures to pharmaceutical dust
  – Tablets especially capable of producing dust
Mail order pharmacies

- Fastest growing sector of the U.S. prescription drug retail market\(^1\)
- High throughput, high volume filling of prescriptions for chronic illnesses
  - Use automatic dispensing machines
- Often hundreds of employees
- Pharmacy technicians far outnumber pharmacists
  - One of the fastest growing jobs in the U.S.\(^2\)


Jobs Evaluated

**Automatic dispensing machine work**
- Filling of canisters
- Routine cleaning of canisters
- Operation and maintenance
- Periodic cleaning and repairing of canisters

**Hand-filling prescriptions**
- Low-volume medications
- Special handling (warfarin)

PPE: occasional use of vinyl or nitrile gloves and N95 filtering facepiece respirators
Occupational exposure limits (OELs)

- OELs exist for dust/particles not otherwise specified
  - Inert and insoluble
- Some active pharmaceutical ingredients (APIs)
  - Warfarin is the only pharmaceutical with an OEL established by federal agencies or national organizations
  - Pharmaceutical companies have established OELs or hazard control bands for many APIs
    - these OELs are often not in the safety data sheets or otherwise provided to the pharmacy

Air Sampling

- **Real-time** air sampling in the personal breathing zone
  - Used an optical particle counter to identify dusty tasks
- **Filter-based** air sampling in the personal breathing zone
  - Total, respirable, and inhalable dust
    - analyzed gravimetrically
    - Some air filter samples analyzed for lactose, a common inactive filler
Active Pharmaceutical Ingredients

- We looked for specific APIs on some air filter samples
  - Desorption electrospray ionization/mass spectrometry used to analyze surface of filters for APIs
  - Analysis is specific, but not quantitative

Quantitative API Analyses

- Selected warfarin and lisinopril for quantitative analysis
- Warfarin (anticoagulant) has an OSHA PEL, NIOSH REL, and ACGIH TLV of 100 µg/m³
- Lisinopril (BP medication) has hazard control band of 1–10 µg/m³ (Bristol-Myers Squibb)
Dust levels in air

- Inhalable dust: 110–800 µg/m³
- Total dust: 6–530 µg/m³
- Respirable dust: none detected–33 µg/m³

- Dust is primarily made of larger particles
- Dust levels were relatively low
  - If dust was inert and insoluble, the levels are <10% of applicable OELs
- All the inhalable dust samples contained lactose
  - Personal air concentrations of lactose (production areas) were greater than the area air concentrations from non-production areas, suggesting that some of the airborne dust came from pharmaceuticals

Dust releases into air

- According to the real-time particle meter, the biggest releases of dust occurred during cleaning of cells and refilling of canisters
- The jobs with the biggest releases were:
  - Filling of canisters
  - Periodic cleaning and repairing of canisters
  - Hand filling warfarin prescriptions
- Because of the large particle sizes, employees more than a few feet from releases are less likely to be exposed
  - Large particles settle to the ground more quickly than small particles
Presence of APIs in air

• 22 APIs were present on 20 total dust air samples
  – Most samples had 2-3 APIs present
  – One sample had 5 APIs present
• This confirms that some of the airborne dust came from pharmaceuticals and that particles from multiple APIs became airborne

Concentrations of specific APIs in air

Warfarin………………………………………………….0.19–3.8 µg/m$^3$
Lisinopril……………………………………………………<0.22–0.44 µg/m$^3$

• These concentrations were <5% of the OELs for warfarin (100 µg/m$^3$) and lisinopril (10 µg/m$^3$)
• We did not quantify the levels of the other 20 APIs due to analytical limitations
Summary

- Dust is released into the air during cleaning, repairing, and filling of canisters
- This dust contained relatively large particles
- Airborne dust concentrations were relatively low
  - The dust contained APIs which are water soluble and biologically active, along with inactive fillers
  - The few APIs we quantified on air samples were below applicable OELs
  - There is a lack of validated air sampling methods and applicable OELs for APIs

Other Issues of Concern

- Inhaling APIs may have different effects than ingesting them
- Health effects from inhalation exposure to multiple APIs are unknown
- Some employees could be allergic to APIs or taking medications that could interact with APIs
- Pharmaceutical dust could contaminate surfaces and clothing and lead to secondary exposures
Selected Recommendations*

• Install movable capture hoods for employees who refill Baker canisters
• Wear disposable or professionally laundered lab-coats or smocks
• Wear nitrile gloves when handling pharmaceuticals
• Improve handwashing
• Install table-top ventilation booths for employees who hand fill hazardous drugs and for employees who clean, repair, and refill cells and canisters
• Follow NIOSH Alert (2004): *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Healthcare Settings*, where applicable

* The full list of recommendations is in the final report

HHE Reports

Search thousands of HHE reports at: http://www.cdc.gov/niosh/hhe

http://www2a.cdc.gov/hhe/search.asp
How to Request an HHE

1-800-CDC-INFO (1-800-232-4636)
http://www.cdc.gov/niosh/hhe/

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