Clinical lessons from “popcorn lung”

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Disclosure Information

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I have nothing to disclose.

I will not discuss off label use and/or investigational use in my presentation.

Irma Ortiz

- 40 y.o. woman
- Mixed dry powder with diacetyl x 5 years
- Symptoms of shortness of breath and cough. Treated for asthma.
- FEV1 = 0.55 L (18% predicted). HRCT with ground glass opacities.
• Request for study of bakery operation in Indiana
• 2 workers with severe lung disease
• Multiple exposures to dusts, flour, flavorings

Young, nonsmoking workers
2/3 mixers affected
Severe loss of FEV$_1$ with fixed airways obstruction
H. Process Description

In the mixing room, batches of liquid and powdered flavorings are mixed in a 300-, 500-, or 1500-pound-capacity mixer. At the time of the site visit, as many as three of the 1500-pound batches and up to ten of the smaller 500- or 300-pound batches could be mixed per day. Each batch consists of any of approximately 200 FDA-approved flavor ingredients with approximately 85% dextrose and starch as a base. Ventilation in the mixing room consists of supply and exhaust fans located opposite ends of the room. Two electrostatic precipitators, located near the mixers, are also used.

Linalool
- Linoleyl Acetate
- Butter Ester
- Butter Derivatives
- Amygdalosene
- Propylene Oxide
- Ethyl Acetate
- Diacetyl
- Methyl Butyl Lactate
- Silicon Dioxide

What is Diacetyl

- Flavouring agent with buttery taste
- Used for creaminess
- Yellow color in dairy products
- More used in microwave popcorn
- Occurs naturally in many foods

Bronchiolitis obliterans

- NIOSH study at "sentinel" microwave popcorn plant
- 4 of 8 workers on lung transplant list
- One death
Toxicology studies

- Multifocal necrotizing bronchitis in rats exposed to 285-371 ppm of diacetyl


Epidemiology studies

- Airways obstruction in popcorn workers related to cumulative diacetyl exposure levels (dose-response relationship)


Exposure studies

- Lowest mean TWA diacetyl concentration in popcorn plant with mixer with BO = 0.02 ppm
- Peak diacetyl concentration while pouring liquid butter in Plant D = 80 ppm

Public health action

- Risk notification of employers, HCPs
- Joint study of CA flavoring companies that use diacetyl
- Petition for Cal/OSHA and FedOSHA standard

Industry-wide Medical Surveillance of Workers in California Flavor Manufacturing Companies: Cross-sectional Results


CA Flavor Manufacturers, 2006-07

- Approximately 27 companies used diacetyl
- 19 companies used 2 to 4000 lbs/yr; 7 heavy diacetyl users used > 800 lbs/yr
- 86% small companies, with < 20 production employees
- Little or no local exhaust ventilation, respiratory protection, hazard communication, or onsite health/safety staff
Production Process

- Hundreds of ingredients
- Never the same thing two days in a row
- High variability in tasks in any given day
- Production vs. Batch process

Powder Production Room

Liquid Production Room
Quality Control Room

Data included in analysis
- 19 companies submitted data for 584 workers
- All data from 3 companies (n=55) excluded due to lack of questionnaires
- 16 companies with data from 10 providers (2 to 97 employees per company)
- Of these 529 workers, 467 (88%) had usable questionnaires & acceptable spirometry quality

Surveillance Findings for 467 Flavoring Workers
- Chest symptoms not in excess
- 18 workers had obstruction:
  - 6 mild cases, 7 moderate, 1 severe, 4 very severe
- Prevalence ratio (PR) for any severe obstruction: 2.7 (CI = 1.2, 6.4)
- PR in young workers: 15.0 (CI = 5.1, 44.1)
- PR in young Hispanic workers: 26.7 (CI = 9.3, 80.2)
Characteristics of 18 Obstructed Flavor Workers
• Age range 19 to 69 years; 78% < 40 yr
• 5 smokers, all < 35 yr
• Median job tenure 3.6 yr (40 days to 26 yr)
• 78% in current production jobs

Characteristics of 18 Obstructed Flavor Workers
• 50% asymptomatic (all mild to moderate)
• 12/13 w/post-bronchodilator spirometry had fixed obstruction
• 4/7 had HRCT features of BO
• 8/12 had physician diagnosis of occupational disease

Limitations of Surveillance
• Underestimation of disease burden
• Healthy worker effect
• Misclassification of exposure
• Misclassification of health outcome
• Quantitative exposures lacking
Pitfalls of Surveillance

- Non-uniform data collection
- Poor timeliness of medical records
- Lack of recommended guidelines
- Spirometry quality
  - Unacceptable curves
  - Poor repeatability
  - Improper instrument set up for result printout

Standard Section 5197 Components

a) General Requirements
b) Definitions
c) Exposure Assessment
d) Regulated areas
e) Engineering Controls and Work Practices
f) Respiratory Protection (Section 5144)
g) Medical Surveillance
h) PLHCP Written Opinion
i) Medical Removal
j) Information and Training
k) Recordkeeping and Reporting
Appendix A (Requirements for sampling protocols)
Appendices B1 and B2 (Flavor Worker Initial and Follow-up Questionnaires)

Who is responsible?

“knowledgable” occupational or pulmonary medicine physician
Who is in the program?

- Reports signs/sxs of diacetyl related disease
- Uncontrolled release of diacetyl or diacetyl-containing materials
- Exposed over CalOSHA limit
- Enters regulated or open area for 14 or more different days within any 12 month period

What should be done?

- Detailed occupational history
- Respiratory health questionnaire
- Spirometry following ATS guidelines by NIOSH certified technician
- Additional tests as necessary

Medical Surveillance Overview
How often are exams done?

- At least every 6 months or when recommended by PLHCP: questionnaire and spirometry
- Signs or symptoms
- Uncontrolled release followed for not less than 12 months

Case of Mr. G

25 yr old male
- Asymptomatic
- 2 yrs on the job
- Decrease in FEV1 of 1L x 4 months
- Relocated to warehouse

Mr. G’s Spirometry
>15% Longitudinal Decline in FEV1

Abnormal Spirometry Evaluation

How are cases caught that leave work?

- Termination exam (unless within last 30 days)
- Reassignment exam: minimum of 12 months
What does PLHCP need to know?

- Standard and medical guidelines
- Job duties
- Exposure levels
- PPE used
- Previous medical evaluations
- Spills, leaks or process upsets

What if the employer changes medical provider?

“If the employer changes supervising physician, the employer shall take all reasonable steps to ensure that all records of medical surveillance, including spirometry results, are transferred to the new supervising physician.”

Employer and worker notification

- Physician gives written opinion within 15 days to employer (including work-relatedness)
- Employer gives physician opinion to employee within 5 days
- Employee has right to second medical opinion
Encouraging reporting

- Employer must modify or transfer the employee to comparable work for up to 6 months with earnings, seniority and other benefits.
- If no work is available, employer must maintain earnings, seniority and other benefits for up to 6 months or until other work becomes available, back to original job or permanently unable to RTW.

Despite the identification of diacetyl as the most likely cause of lung disease in such patients, no preventive measures have been adopted.
Take home points

• Spirometry essential in detecting early disease
• Prompt diagnosis and removal from exposure
• Physician case reporting critical to public health intervention