Epidemiology of aluminosilicate wools (refractory ceramic fibers, RCF): Results to date and the influence of the PSP

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BACKGROUND AND INTRODUCTION
Background

- Aluminosilicate wool (ASW), also called refractory ceramic fiber (RCF), was discovered in the 1940s and commercialized during the 1950s.
- Early studies with laboratory animals indicated that it was no more toxic than a “nuisance dust,” but later animal studies raised concerns over possible health effects.
Epidemiology studies

• Industry developed a *product stewardship program* (PSP) to identify and control any risks associated with use of RCF

• Epidemiology studies beginning in 1987 were one key component of the PSP

• Epidemiology studies were conducted in both Europe (*Institute of Occupational Medicine* [IOM], Edinburgh) and the United States (University of Cincinnati)
Scope of epidemiology studies

- **Symptoms**: Collected data on respiratory symptoms
- **Spirometry**: Conducted periodic pulmonary function tests
- **X-ray**: Collected chest radiographs
- **Mortality**: Analysed mortality data from plants in US
Follow up for different endpoints

- Mortality
- Exposure assessment
- X-ray
- PFT
- Symptoms

FINDINGS

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Published studies

- **Symptoms**
  - Trethowan et al (1995; Europe)
  - Cowie et al (2001; Europe)
  - LeMasters et al (1998; US)

- **Radiographic findings**
  - Lockey et al (2012; US)
  - Cowie et al (2001; Europe)

- **Lung function**
  - McKay et al (2011; US)
  - Trethowan (1995; Europe)
  - Cowie (2001; Europe)

- **Mortality**
  - LeMasters et al (2003; US)
Populations studied

- **Europe – Cross-sectional studies**

- **US – Longitudinal studies**
  - McKay et al (2011) – 1396 workers
Findings overview

**Symptoms**
- Similar to other dust-exposed populations

**X-rays**
- Dose related pleural plaques (US study)
- No interstitial fibrosis

**Spirometry**
- Some effects seen, but not in longitudinal study

**Mortality**
- US: No mesothelioma or excess lung cancer
What are pleural plaques?

• Collagenous thickening of parietal pleura
• Found in the lateral and lower-half of the pleural cavity
• Plaques almost always bilateral with well-defined borders
• Latency reported to be 15-40 years
• Commonly associated with exposure to asbestos, but also occur spontaneously
Plaques as shown in *computed tomography* (CT)

Arrows show pleural plaques
Microscopically, the pleural plaque is composed of dense layers of collagen.
Clinical significance of plaques

• No evidence that plaques are precursor lesions for either lung cancer or mesothelioma
• Plaques are viewed as evidence of (fibre) exposure, and it is this exposure that is of possible importance for future health
• Plaques are not associated with symptoms or clinically significant loss of lung function
• Plaques not likely an independent risk factor for tumours
What is the incidence of plaques?

• Incidence varies with population:
  - Urban incidence greater than rural
  - Males typically higher than females
  - General populations 0.5 – 8%
  - Occupationally exposed cohorts 0.1 – 69%

• Overall incidence in US RCF population: 2.7% (no asbestos exposure) to 4.6% (asbestos)
  - Incidence varies with latency, duration, and cumulative exposure.
  - Currently stable at 2.5 – 3%
CONCLUSIONS
Key findings

- Symptoms in RCF workers similar to other dust-exposed groups
- No increase in interstitial fibrosis
- No increased malignancy of respiratory tract; no mesotheliomas
- No accelerated decline in lung function
- Pleural plaques statistically significant, but thought to be indicator of exposure rather than precursor of disease
- No evidence supporting findings from the early rat carcinogenicity studies
Continuing studies under the PSP

• The US mortality and exposure study will continue.

• Companies will continue with respiratory health surveillance in line with the principles of the PSP.