Mesothelioma registry systems
Italy and Lombardy

Dario Consonni
Epidemiology Unit, Fondazione IRCCS Ca’ Granda Ospedale Maggiore Policlinico, Milan, Italy
Conflicts of interest

I served as expert for the judge in asbestos criminal trials
Outline

- National Mesothelioma Registry (ReNaM)
- Lombardy Mesothelioma Registry (RML)
  - Geographical distribution
  - The asbestos-cement factory Fibronit: impact
  - Mesothelioma projections as of 2029
  - Ongoing projects
- Lung cancer and asbestos in the EAGLE case-control study
Outline

• **National Mesothelioma Registry (ReNaM)**
• **Lombardy Mesothelioma Registry (RML)**
  – Geographical distribution
  – The asbestos-cement factory Fibronit: impact
  – Mesothelioma projections as of 2029
  – Ongoing projects
    ▪ Lung cancer and asbestos in the EAGLE case-control study
Italy: asbestos production/import 1945-92

Amphiboles and chrysotile 3.75 million tons

Law 257/1992 asbestos ban

(ReNaM 2006)
Figure 1. Relationship between 15-year cumulative mortality of mesothelioma (1994–2008) and cumulative use of asbestos (1920–1970) weighted by the size of national populations in 56 countries/entities with data for both mesothelioma and asbestos use. Asbestos use for 33 countries/entities without mesothelioma frequency data is indicated along the x-axis. The figure is based on the following regression model: \( \log_{10}(15\text{-year cumulative mortality of mesothelioma}) = \beta_0 + \beta_1 \times \log_{10}\text{(cumulative use of asbestos)} \), where \( \beta_0 = -1.998 \) (95% CI, -2.676 to -1.319) and \( \beta_1 = 0.913 \) (95% CI, 0.800 to 1.026). Adjusted \( R^2 = 0.827; \ p < 0.0001 \).
Italy: pleural MM mortality projections 2000-2029

Figure 2. Italian raw asbestos per capita consumption (five-year moving average - tons per 1,000,000 inhabitants), observed (1969-1999) and predicted (2000-2029) pleural mesothelioma deaths\(^1\) (MP) among men aged 25-89 years old in Italy.

\(^1\) Pleural mesothelioma deaths = pleural cancer deaths \(* 0.73\).
ReNaM, INAIL (Italian Compensation Authority)

- National MM Registry (ReNaM, INAIL, Rome) **Law 308/2002**
- **Network** of Regional Operative Centers (COR)
- Some Regions started earlier
Mesothelioma Registry: Objectives

- **Temporal trends and geographical distribution** of cases and incidence rates (could be done in any cancer registry)

- Cases by **sector**; **asbestos exposure** (patients or next-of-kin interviewed with a Standardized Questionnaire)

- **Medico-legal assistance** to patients and families (compensation for **occupational** and – since a few years – also **non-occupational** cases)

- **Epidemiological studies** on the asbestos-mesothelioma association
Epidemiology of malignant mesothelioma in Italy: surveillance systems, territorial clusters and occupations involved

Alessandro Marinaccio, Alessandra Binazzi, Michela Bonafede, Davide Di Marzio, Alberto Scarselli; Regional Operating Centres

*J Thorac Dis* 2018;10(Suppl 2):S221-S227

Table 1 Italian National Mesothelioma Register (ReNaM) archives. Collected malignant mesothelioma cases by gender, age at diagnosis, period of incidence, anatomical site, diagnostic certainty level and morphology. ReNaM archives updated at December 2016, diagnosis period 1993–2015, Italy

<table>
<thead>
<tr>
<th>Variables</th>
<th>Men</th>
<th></th>
<th>Women</th>
<th></th>
<th>All</th>
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<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
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<tr>
<td>Age class</td>
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<tr>
<td>≤44</td>
<td>326</td>
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<td>166</td>
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<td>45–64</td>
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<td>1,856</td>
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<td>7,199</td>
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<td>65–74</td>
<td>7,360</td>
<td>37.5</td>
<td>2,477</td>
<td>32.1</td>
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<tr>
<td>≥75</td>
<td>6,604</td>
<td>33.6</td>
<td>3,224</td>
<td>41.7</td>
<td>9,828</td>
<td>35.9</td>
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<td>Anatomical site</td>
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<tr>
<td>Pleura</td>
<td>18,473</td>
<td>94.1</td>
<td>6,977</td>
<td>90.3</td>
<td>25,450</td>
<td>93.0</td>
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<td>Peritoneum</td>
<td>1,042</td>
<td>5.3</td>
<td>727</td>
<td>9.4</td>
<td>1,769</td>
<td>6.5</td>
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<td>39</td>
<td>0.2</td>
<td>19</td>
<td>0.2</td>
<td>58</td>
<td>0.2</td>
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<tr>
<td>Tunica vaginalis testis</td>
<td>79</td>
<td>0.4</td>
<td>79</td>
<td>0.3</td>
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</table>

19,633 M 7,723 F 27,356 All

About 1,500 cases/year; M/F ratio = 2.5
<table>
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<tr>
<th>Variables</th>
<th>Men</th>
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<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
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<tr>
<td><strong>Diagnostic evaluation</strong></td>
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<tr>
<td>Definite MM</td>
<td>16,075</td>
<td>81.9</td>
<td>5,928</td>
<td>76.8</td>
<td>22,003</td>
<td>80.4</td>
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<td>Probable or possible MM</td>
<td>3,558</td>
<td>18.1</td>
<td>1,795</td>
<td>23.2</td>
<td>5,353</td>
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<td><strong>Morphology</strong></td>
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<tr>
<td>Epithelioid</td>
<td>1,0845</td>
<td>55.2</td>
<td>4,422</td>
<td>57.3</td>
<td>15,267</td>
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<td>Biphasic</td>
<td>2,188</td>
<td>11.1</td>
<td>692</td>
<td>9.0</td>
<td>2,880</td>
<td>10.5</td>
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<tr>
<td>Fibrous</td>
<td>1,684</td>
<td>8.6</td>
<td>421</td>
<td>5.5</td>
<td>2,105</td>
<td>7.7</td>
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<tr>
<td>MM NOS*</td>
<td>2,469</td>
<td>12.6</td>
<td>986</td>
<td>12.8</td>
<td>3,455</td>
<td>12.6</td>
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<tr>
<td>Not available</td>
<td>2,447</td>
<td>12.4</td>
<td>1,202</td>
<td>15.5</td>
<td>3,649</td>
<td>13.3</td>
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<tr>
<td><strong>Overall</strong></td>
<td>19,633</td>
<td>100.0</td>
<td>7,723</td>
<td>100.0</td>
<td>27,356</td>
<td>100.0</td>
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<td>--------------------------------------</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Male (%)</td>
<td>Female (%)</td>
<td>Total (%)</td>
<td></td>
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<tr>
<td>Occupational, definite</td>
<td>9,300 (59.3)</td>
<td>987 (17.3)</td>
<td>10,287 (48.1)</td>
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<tr>
<td>Occupational, probable</td>
<td>1,358 (8.7)</td>
<td>191 (3.3)</td>
<td>1,549 (7.2)</td>
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<tr>
<td>Occupational, possible</td>
<td>2,246 (14.3)</td>
<td>736 (12.9)</td>
<td>2,982 (13.9)</td>
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<td></td>
<td></td>
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<tr>
<td>Familial</td>
<td>152 (1.0)</td>
<td>895 (15.7)</td>
<td>1,047 (4.9)</td>
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<tr>
<td>Environmental</td>
<td>409 (2.6)</td>
<td>530 (9.3)</td>
<td>939 (4.4)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Other non-occupational</td>
<td>128 (0.8)</td>
<td>194 (3.4)</td>
<td>322 (1.5)</td>
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<td></td>
<td></td>
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<tr>
<td>Unlikely</td>
<td>268 (1.7)</td>
<td>308 (5.4)</td>
<td>576 (2.7)</td>
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<td></td>
<td></td>
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<tr>
<td>Unknown</td>
<td>1,824 (11.6)</td>
<td>1,861 (32.6)</td>
<td>3,685 (17.2)</td>
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<td></td>
<td></td>
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<tr>
<td>Total defined</td>
<td>15,685 (100.0)</td>
<td>5,702 (100.0)</td>
<td>21,387 (100.0)</td>
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<td></td>
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<tr>
<td>Total</td>
<td>19,633 (100.0)</td>
<td>7,723 (100.0)</td>
<td>27,356 (100.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Case list for year 2015 is not complete and collection of data is to be considered ongoing.
Rates by municipality 1993-2015
Piedmont, the region of Casale Monferrato (1993-2011) 3,560 cases

Liguria (1994-2012) 2,314 cases

Lombardy (2000-2012) 4,215 cases

Italy (1993-2012): 21,463 cases
Outline

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  ▪ Lung cancer and asbestos in the EAGLE case-control study
Lombardy Mesothelioma Registry (RML)

Lombardy, N-W Italy, 23,864 km², 10 million people, highly industrialized
~100 hospitals

Thoracic surgery
Pneumo/ORL
Oncology
RT

Pathology depts ICD-O codes

Compulsory reports (continuous)

Clinica del Lavoro, Milano

Every~6 months

Registry

70%

Every year

Cancer registries

INAIL

Mortality

Hospital admissions ICD-9 163

Every year
Diagnostic evaluation

Review of all clinical documentation

- **Definite**: histology + immunohistochemistry 80%
- **Probable**: histology 8%
- **Possible**: imaging 12%

Asbestos exposure

Verified cases interviewed: 94% (95% M, 91% F)

Patients: 54% (59% M, 45% F)

- Occupational (definite, probable, possible)
- Familiar
- Domestic
- Environmental
- Unknown (no evidence of asbestos exposure)
- Unlikely
- Undefined (interview not informative)
A total of 76 of the 127 cases were also listed in the Regional Mesothelioma Registry of Piedmont: among them 56 were classified by the Registry as certain mesothelioma, 19 as probable or possible mesothelioma, and 1 as non-mesothelioma. If we consider our diagnostic validation as gold standard, the sensitivity of the classification of the Registry (certain confirmed mesothelioma versus other) was 83% and the specificity 34% (results not shown in detail).

False positive rate = 66%, but results not shown in detail! This sentence is simply **FALSE**
They are working for the companies in many asbestos criminal trials
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Geographical patterns of mesothelioma incidence and asbestos exposure in Lombardy, Italy

Carolina Mensi*, Sara De Matteis**, Dolores Catelan***, Barbara Dallari*, Luciano Riboldi*, Angela Cecilia Pesatori*, ****, Dario Consonni*

* Department of Preventive Medicine, Fondazione IRCCS Ca’ Granda Ospedale Maggiore Policlinico, Milan, Italy
** National Heart & Lung Institute, Respiratory Epidemiology, Occupational Medicine and Public Health, Imperial College London, London, UK
*** Department of Statistics, Computer Science, Applications “Giuseppe Parenti”, University of Florence, Florence, Italy
**** Department of Clinical Sciences and Community Health, Università degli Studi di Milano, Milan, Italy
### Results 2000-2012: 4,442 cases

<table>
<thead>
<tr>
<th></th>
<th>M</th>
<th>F</th>
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<tbody>
<tr>
<td>Pleura</td>
<td>2693</td>
<td>1462</td>
</tr>
<tr>
<td></td>
<td>94.5%</td>
<td>91.8%</td>
</tr>
<tr>
<td>Peritoneum</td>
<td>134</td>
<td>125</td>
</tr>
<tr>
<td></td>
<td>4.7%</td>
<td>7.9%</td>
</tr>
<tr>
<td>Pericardium</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>0.2%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Tunica Vaginalis Testis</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.6%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>850</td>
<td>1592</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>100%</td>
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</table>

M/F Ratio: 2850/1592 = 1.8
Asbestos exposure

<table>
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<tr>
<th>Gender</th>
<th>No interview</th>
<th>Unknown</th>
<th>Extra 4%</th>
<th>Extra 14%</th>
<th>Occupational</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>17%</td>
<td>74%</td>
<td></td>
<td>Extra 14%</td>
<td>38%</td>
</tr>
<tr>
<td>F</td>
<td>39%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Cases by Sector

Metal-mechanic, metallurgy

Construction

Non-asbestos textile

Asbestos-cement

Cases by Sector

- MMM
- Edilizia
- Tessile
- Auto
- Chimica
- Alimentare
- Militare
- Trasporti
- Gomma
- Cemento-amianto
- Ferrovie
- Energia
- Socio-sanitario

M | F
Textile industry – Asbestos in ceilings, walls, brakes

Il rischio amianto nel settore tessile: indicazioni dal Registro Mesoteliomi Lombardia e definitiva conferma

G. CHIAPPINO, C. MENS*, L. RIBOLDI, G. RIVOLTA
Centro Studi Effetti Biologici Polveri Inalate - Dipartimento di Medicina del Lavoro - Milano
* Responsabile Registro Mesoteliomi Lombardia

Med Lav 2003; 94, 6: 521-530
Cases by Province

- **VA**: 438
- **CO**: 233
- **LC**: 156
- **BG**: 487
- **MB**: 383
- **MI**: 1444
- **PV**: 473
- **LO**: 107
- **CR**: 145
- **BS**: 367
- **SO**: 80
- **MN**: 129
Rates by Municipality

Crude rates (per 100,000) - Men

Crude rates (per 100,000) - Women

BYM crude rates (per 100,000) - Men

BYM crude rates (per 100,000) - Women
M1/F1 - Pavia

- Asbestos-cement factory (Fibronit) in Broni (1932-92)
- Broni rates: M: **100.0** (57 cases), F: 68.4 (44 cases)
- Stradella rates: M: 33.6 (23 cases); F: 43.5 (33 cases)
- (Borni < 10,000 people; Stadella 11,600 people)
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  – Ongoing projects
• Lung cancer and asbestos in the EAGLE case-control study
Impact of an asbestos cement factory on mesothelioma incidence: Global assessment of effects of occupational, familial, and environmental exposure

Carolina Mensi\textsuperscript{a,1}, Luciano Riboldi\textsuperscript{a,1}, Sara De Matteis\textsuperscript{b,2}, Pier Alberto Bertazzi\textsuperscript{a,c,1,3}, Dario Consonni\textsuperscript{a,*}

\textsuperscript{a} Department of Preventive Medicine, Fondazione IRCCS Ca’ Granda Ospedale Maggiore Policlinico, Milan, Italy
\textsuperscript{b} National Heart & Lung Institute, Respiratory Epidemiology, Occupational Medicine and Public Health, Imperial College London, London, UK
\textsuperscript{c} Department of Clinical Sciences and Community Health, Università degli Studi di Milano, Milan, Italy
• **Broni**: small town <10,000 people (Pavia Province)

• **Fibronit**: second largest Italian asbestos-cement factory in terms of person-years: 2.741 M, 714 F (1932-93). ~100,000 tons/year in the ‘60s

- Portland Cement 325 mixed with asbestos 7:1
- Chrysotile
- Crocidolite (10-15% in tiles, 30% in pipes)
- Amosite, small quantities
## Results (2000-2011)

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>Occupational</td>
<td>32</td>
<td>6</td>
<td>38</td>
</tr>
<tr>
<td>Familiar</td>
<td>5</td>
<td>32</td>
<td>37</td>
</tr>
<tr>
<td>Environmental</td>
<td>23</td>
<td>49</td>
<td>72</td>
</tr>
<tr>
<td>- Broni</td>
<td>20</td>
<td>28</td>
<td>48</td>
</tr>
<tr>
<td>- Adjacent towns*</td>
<td>2</td>
<td>17</td>
<td>19</td>
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<tr>
<td>- Surrounding towns</td>
<td>1</td>
<td>4</td>
<td>5</td>
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<tr>
<td><strong>Total</strong></td>
<td>60</td>
<td>87</td>
<td>147**</td>
</tr>
</tbody>
</table>

*Stradella (11,600 people), M: 2 cases F: 14 cases
**138 pleura, 9 peritoneum
• **147 cases** (130 more than expected in 12 years (2000-2011) caused by asbestos from Fibronit

• **Occupational impact in men**: 32 cases

• **Familiar/Environmental impact in women**: 32 + 49

• **Broni e Stradella**: 48+16 cases

• [Not counted: 57 cases (47 M, 10 F) exposed to asbestos in other occupational contexts]
Not only Mesothelioma...

Mortality in asbestos cement workers in Pavia, Italy: A cohort study


Enrico Oddone | Daniela Ferrante | Sara Tunesi | Corrado Magnani

1818 workers (1663 M, 165 F) 1970-2014

<table>
<thead>
<tr>
<th>Cancer site</th>
<th>Observed</th>
<th>Expected</th>
<th>Excess cases O – E</th>
</tr>
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<tbody>
<tr>
<td>Pleura</td>
<td>74</td>
<td>2.8</td>
<td>71.1</td>
</tr>
<tr>
<td>Peritoneum</td>
<td>14</td>
<td>1.5</td>
<td>12.5</td>
</tr>
<tr>
<td>Lung</td>
<td>169</td>
<td>113.9</td>
<td>55.1</td>
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<tr>
<td>Ovary</td>
<td>4</td>
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<td>Asbestosis</td>
<td>17</td>
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<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>278</td>
<td>119.3</td>
<td>158.7</td>
</tr>
</tbody>
</table>
Outline

• National Mesothelioma Registry (ReNaM)
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  – Ongoing projects

  ▪ Lung cancer and asbestos in the EAGLE case-control study
ORIGINAL ARTICLE

Incidence of mesothelioma in Lombardy, Italy: exposure to asbestos, time patterns and future projections

Carolina Mensi,¹ Sara De Matteis,² Barbara Dallari,¹ Luciano Riboldi,¹ Pier Alberto Bertazzi,¹ Dario Consonni¹


Open Access
Cases 2000-2012

Cases: +3.6% / year
Crude rates: +2.6% / year

Adjusted rates by age:
65+ y: increasing
<65 y: decreasing

Year of diagnosis
Men
Women

MM cases
Cases: +3.3% / year
Crude rates: +2.5% / year
Poisson Age-Cohort model: results

Solid lines: observed/predicted counts
Dashed lines: 90% bounds around predicted counts
• Peak in 2019 (417 cases, 267 M, 150 F)

• Cases 2013-2029: Total: 6832
  M: 4397
  F: 2435

• Cases 2000-2029: Total: 11274
  M: 7247
  F: 4027

• Similar to Italian mortality projections (Marinaccio IJC 2005)

• Italy: only West European country in which asbestos consumption increased in 1975-85 (Marinaccio IJC 2015)

• Cases are decreasing in some Regions, increasing in others (ReNaM 2015)
Mesotheliomas in Lombardy 2000-2029

Data 2013-2015

Men: ~7,200 cases

Women: ~4,000 cases

Cases


Cases

LimInf90M
LimSup90M
CasiOsservatiM
CasiPrevistiM
CasiOsservatiF
CasiPrevistiF
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Ongoing projects

- Case-control study on pleural MM in 6 Regions
- Case-control study on pericardial and TVT MM in 6 Regions (relationship with asbestos put into doubt in a recent review paper)
- Case-control study on peritoneal MM in Lombardy
- Economical costs
- Comparison of MM cases with autopsy data in Pavia
- Rate Advancement Periods (RAP): M vs F
Outline

- National Mesothelioma Registry (ReNaM)
- Lombardy Mesothelioma Registry (RML)
  - Geographical distribution
  - The asbestos-cement factory Fibronit: impact
  - Mesothelioma projections as of 2029
  - Ongoing projects
- Lung cancer and asbestos in the EAGLE case-control study
Impact of occupational carcinogens on lung cancer risk in a general population

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EAGLE

- Population-based case-control study in Lombardy, 2002-05
- National Cancer Institute (Bethesda, USA), Milan University, 13 Hospitals

http://eagle.cancer.gov/
• Lung cancer risk increased **78%** in asbestos exposed (all three main histological types)
• Population Attributable Fraction: **18.1%**
• In **2005**, 4,515 lung cancer cases in Lombardy, then
• **0.181*4,515 = 817** asbestos-related lung cancer cases in Lombardy
• (In the same year: **318 mesotheliomas**)
By applying our PAFs to the lung cancer incidence rates in males in Lombardy in 2005, we estimated that 817 (95% CI: 569–1052), 257 (95% CI: 18–479), 316 (95% CI: 9–600) and 1016 (95% CI: 637–1355) lung cancer cases were attributable to occupational exposure to asbestos, silica, Ni–Cr and these three exposures combined, respectively. If we consider also the increased risk found for high exposure to PAH, corresponding to a PAF of 2.9% (95% CI: 0.1–5.9), there would be 131 additional potentially avoidable cases (95% CI: 5–266). These numbers sharply contrast with those officially reported to and compensated by the Italian Workers’ Compensation Authority. For instance, in the period 1999–2004, only 399 work-related lung cancer cases (on average 66.5/year) were reported in Lombardy and about half of them compensated.
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