Conclusions of the pilot study:

The percentage of children with free-access-to-care status seems high compared to data from the general population. We observe small percentages of long-term disease status in this population of young children.

Characteristics of infants: The sex ratio observed is consistent with published data for children younger than 5.

Prevalence of asthma: Based on an annual number of 800,000 births in France (i.e. 8,000 recorded in the EGB) and the 1,790 children recruited from two dispensations of respiratory therapy, the prevalence of asthma was estimated at 19.1%.

RESULTS

Our pilot sample included 1,149 infants with a potential diagnosis of asthma and responding to other selection criteria (mean age 13 months, 64% boys). Among them, 51 and 768 were assigned to MTL-4 and ICS groups, respectively. We preselected infants:

- Receiving ≥ 2 consecutive dispensations of any respiratory drugs (R03 ATC classification), as from March 8, 2010 (launch of MTL-4 in France). The second R03 had to be dispensed between 8 and 91 days after the first R03. Infants had to be 6 to 24 months old at the time of the first dispensation of R03 therapy.
- Presenting an initial exacerbation within 6 months following the first dispensing of R03. Asthma exacerbation was identified using asthma-related hospitalizations, dispensing of oral corticosteroids, addition of short-acting beta agonist to existing respiratory therapy, switch to an ICS therapy with higher dosage or switch to nebulized CS.
- With at least 6 months follow-up in the EGB database.

METHOD

- Inclusion criteria in the cohort:
  - Receiving ≥ 2 consecutive dispensations of any respiratory drugs (R03 ATC classification), as from March 8, 2010 (launch of MTL-4 in France). The second R03 had to be dispensed between 8 and 91 days after the first R03. Infants had to be 6 to 24 months old at the time of the first dispensation of R03 therapy.
  - Presenting an initial exacerbation within 6 months following the first dispensing of R03. Asthma exacerbation was identified using asthma-related hospitalizations, dispensing of oral corticosteroids, addition of short-acting beta agonist to existing respiratory therapy, switch to an ICS therapy with higher dosage or switch to nebulized CS.
  - With at least 6 months follow-up in the EGB database.

- Exclusion criteria:
  - Infants aged 6-24 months
  - Number Percentage

RESULTS

- Table 1: Inclusion criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving ≥ 2 consecutive dispensations of any respiratory drugs (R03 ATC classification), as from March 8, 2010 (launch of MTL-4 in France). The second R03 had to be dispensed between 8 and 91 days after the first R03. Infants had to be 6 to 24 months old at the time of the first dispensation of R03 therapy.</td>
<td>1,790</td>
<td>100%</td>
</tr>
<tr>
<td>Presenting an initial exacerbation within 6 months following the first dispensing of R03. Asthma exacerbation was identified using asthma-related hospitalizations, dispensing of oral corticosteroids, addition of short-acting beta agonist to existing respiratory therapy, switch to an ICS therapy with higher dosage or switch to nebulized CS.</td>
<td>1,619</td>
<td>90.5%</td>
</tr>
<tr>
<td>Infants aged 6-24 months with &lt; 6 months follow-up after the first exacerbation were excluded</td>
<td>51</td>
<td>3.9%</td>
</tr>
</tbody>
</table>

DISCUSSION-CONCLUSIONS

- Prevalence of asthma: Based on an annual number of 800,000 births in France (i.e. 8,000 recorded in the EGB) and the 1,790 children recruited from two dispensations of respiratory therapy, the prevalence of asthma is estimated to be 22%.

- Characteristics of infants: The sex ratio observed is consistent with published data for children younger than 5.

- MARKET ACCESS

- Infants excluded from the analysis:
  - 1,149 infants were not included in the analysis as they did not have a marker for initial exacerbation during the required time-interval. In addition, 465 infants with < 6 months follow-up after the first exacerbation were excluded.