Nationwide outbreak of *Salmonella* Kedougou linked to infant formula milk. Spain, 2008

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• Infant powder formula milk is not a sterile product

• *Salmonella* was associated with powder formula milk in many outbreaks:
  
  – *S. Tennessee* (Canada and USA, 1993)
  – *S. Virchow* (Spain, 1994)
  – *S. London* (Korea, 2000)
  – *S. Agona* (France, 2005)
  – *S. Give* (France, 2008)
Background

- *Salmonella* Kedougou: uncommon worldwide
  - Only two outbreaks reported
    - Linked to Salami consumption (Norway, 2006)
    - Linked to ham and turkey meat (UK, 1992)

- In Spain:
  - National Center of Microbiology:
    - Identified a mean of 3 isolations/year in humans, between 2002 and 2007
The National Centre of Microbiology reported an increase in isolates of S. Kedougou during 2008:

- Up to date, 21 isolates vs. 6 in 2007
- 90% of cases were under 1 year old
The National Centre of Epidemiology (NCE):

- **Sent an alert** to:
  - Regional Epidemiology Services
  - Food Safety Agency (FSA)
  - Ministry of Health
  - European Food and Waterborne Diseases Network:
    11 countries answered: Not *S. Kedougou* increases

- **Began a study** to confirm the outbreak
Objectives

• To confirm and to know the magnitude of the outbreak

• To identify the source of infection, mode of transmission and risk factors

In order to implement appropriate control measures
Outbreak investigation

- Active Case Finding
- Matched Case-Control Study
- Microbiological Investigation
- Environmental Investigation
Active Case Finding

• Any *Salmonella* Group G isolates in 2008 should be sent to the National Center of Microbiology for serotyping

• A questionnaire designed:
  – Filled in by regional epidemiologists
  – Information about: illness, contacts, food consumed (72 h), food preparation, conservation and disinfection
  – Sent to the NCE: collect and analyze information
Results

42 cases were identified

- Questionnaire Response Rate: 93%
- 42% male
- 74% < 1 year old
- 28% required hospitalization
- 2 adults: parents of cases
Cases of *Salmonella* Kedougou by age and week of isolation. (N=42)
Cases of *Salmonella* Kedougou by regions, 2008 (N=42)

Cases were located in 11 of 19 Spanish Regions
Case characteristics: <1 year old

- **Response rate:** 31/32
- **Median age:** 4.3 months
- **Clinical Findings:**
  - Diarrhea (100%)
  - Blood in stool (64%)
  - Fever (38%)
  - Vomiting (27%)
- **Hospitalization:** 10 cases (32%)
# Findings in cases <1 year old

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk &quot;Brand A&quot;</td>
<td>31</td>
<td>100</td>
</tr>
<tr>
<td>Mineral water (different brands)</td>
<td>24</td>
<td>77</td>
</tr>
<tr>
<td>Baby puree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fruit (homemade)</td>
<td>7</td>
<td>23</td>
</tr>
<tr>
<td>Fruit (commercial food)</td>
<td>5</td>
<td>16</td>
</tr>
<tr>
<td>Vegetables and chicken (homemade)</td>
<td>8</td>
<td>26</td>
</tr>
<tr>
<td>Baby cereal</td>
<td>11</td>
<td>35</td>
</tr>
<tr>
<td>Animal contact</td>
<td>9</td>
<td>29</td>
</tr>
</tbody>
</table>

N = 31 cases
Case characteristics: ≥ 1 year old

- Response rate: 8/10
- Median age: 28 years old (range: 1-84 y.o.)
- Hospitalization: 1 case
- Two cases were parents of cases <1 year old
- Three cases consumed infant powder formula milk “Brand A”
Hypothesis generation

From the first 12 questionnaires collected:

- 11 children consumed milk “Brand A”
- 1 adult was a father of a case < 1 year old

**Hypothesis:** The consumption of infant formula milk “Brand A” is associated with the illness

We began an analytical study
Matched Case-Control Study

- **Case definition:**
  - Children under 1 year
  - S. Kedougou isolated in 2008

- **4 controls per case**

- **Matched for:**
  - Age (±1 month)
  - Sex
  - Health centre
  - Time of visit (± 1 week)
  - No gastrointestinal symptoms

- **Exact conditional logistic regression**
Results
(22 cases and 70 controls included)

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>OR</th>
<th>CI (95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruit baby puree</td>
<td>0.8</td>
<td>0.08 - 7.51</td>
</tr>
<tr>
<td>Vegetables and chicken baby puree</td>
<td>0.34</td>
<td>0.01 - 26.07</td>
</tr>
<tr>
<td><strong>Infant Formula Milk &quot;Brand A&quot;</strong></td>
<td><strong>74.92</strong></td>
<td><strong>12.89 - ∞</strong></td>
</tr>
<tr>
<td>Animal contact</td>
<td>0.98</td>
<td>0.3 - 3.12</td>
</tr>
</tbody>
</table>

* Median unbiased estimates (MUE);
  ML estimation= Inf.
Microbiological investigation

- **Pulse Field pattern (PFGE):**
  All isolates showed the same pattern

- **Antibiogram:**
  The strains were fully sensitive to the standard antimicrobials
Environmental investigation

Milk samples by Food Safety Agency

- Only 3 milk samples from cases were obtained
- No S. Kedougou was isolated

Factory Inspection by Regional Services of Public Health

- Not done because production factory was closed on Feb/08
- Records provided by factory quality control service:
  - *No Salmonella* isolated in raw materials or products
  - Other Enterobacteriaceae sp. detected in batches
The product was only distributed in Spain

- 5 batches of milk “Brand A” recalled
- Report to the Rapid Alert System for Food and Feed (RASFF)
Control Measures by FSA

- Press release to inform public
- Information phone number
Outbreak follow-up

Three cases detected 20 days after control measures

- All children under 1 year old
- All consumed milk “Brand A”:
  - One batch number: Not related to batches recalled
  - One milk sample provided by a case: (-) S. Kedougou

Until now, no more cases detected
Limitations

Recall Bias:

- Mean of 108 days between symptoms and interview (range: 9 – 222 days)
  - Parents usually remember infant feeding patterns, brands

Batch numbers and milk samples not collected

Overmatching?

- Medical center: Doctor prescription habits
  - Low number of controls consumed “Brand A” (10%)
Conclusions

• Outbreak of S. Kedougou linked to infant formula milk was confirmed in Spain (Feb-Aug, 2008)

• First outbreak of this serotype associated with infant formula milk

• No more cases detected after 09/15/08
Outbreak Difficulties

- Limited human resources:
  - On vacation
- Communication:
  - Authorities and institutions
  - No Feedback
- Not product information
- Press release not revised:
  - Collaborators not included
That is the outbreak...
Suggestions
Choose the best communication channel
DATA COLLECTED

Order
Movility
Security
Legal implication
Thank you!