Impact of Food Allergy on quality of life

Brussels, December 11, 2007

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Food Allergy in Europe:
after Europrevall – where do we go from here?

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Food Allergy in Europe

- High prevalence, high level of societal concern
- Emergent, underdeveloped knowledge base
- No accurate information on impact and cost
- Fragmented clinical care of variable quality
- Diagnosis unstandardized and cumbersome
- No therapy
- No relevant, reliable outcome measures
Food Allergy in Europe

- Key role of prevention of exposure to allergenic foods
- Multidisciplinary approach, including:
  - medical profession
  - patient organisations
  - food industry
  - food marketing chains
  - catering industry
  - medical technology firms
  - information technology firms
  - government
Food Allergy in Europe: Role of Government

- Coordination of activities of multidisciplinary contributors
- Development of standards, regulation and legislation
- Facilitate development of knowledge base necessary to underpin legislation
- Goals:
  - protect consumers
  - stimulate industry
  - assist care givers and patients
Europrevall

- Accurate prevalence figures
- Analysis of risk factors for development of primary prevention schemes
- Standardisation of diagnostic methods
- Increasing knowledge base of food allergens
- Examination of consumer preferences, technological possibilities
- Measurement of direct financial cost
- Development of first ever (!) outcome measures for food allergy and measurement of impact on quality of life
Measurement of health-related quality of life in patients with food allergy

WP 4.2
Brussels, December 2007

P29, University Medical Center Groningen, the Netherlands
BMJ Flokstra-de Blok, BJ Vlieg-Boerstra, JNG Oude Elberink, EJ Duiverman, AEJ Dubois
Development

- Item generation
- Item reduction
- Cross-sectional validation
- Longitudional validation
Item generation

Sources for items

- **Interviews FA patients**
  - 8-12 years, 13 FA patients
  - 13-17 years, 10 FA patients
  - > 18 years, 22 FA patients

- **Focus group FA patients**
- **Experts in the field**
- **Literature**
Results item generation

• 3 Extended item lists
  • 8-12 years, 139 items
  • 13-17 years, 166 items
  • ≥ 18 years, 180 items

• Themes
  - shopping
  - food preparing
  - eating
  - eating out
  - social activities
  - holidays
  - emotions
  - work or school
  - medication
Item reduction

• Clinical impact

  – Patients were asked to identify the impairments that are most important to them in their daily lives.

  – Items identified most frequently and most important were selected
# Format item reduction

<table>
<thead>
<tr>
<th>Question</th>
<th>No</th>
<th>Yes</th>
<th>How troublesome?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you go to more shops because of your food allergy?</td>
<td>●</td>
<td>○</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>Do you read labels because of your food allergy?</td>
<td>○</td>
<td>●</td>
<td>1 2 3 4 □</td>
</tr>
<tr>
<td>Do you read labels because of your food allergy?</td>
<td>○</td>
<td>●</td>
<td>😊😊😊😊😊</td>
</tr>
</tbody>
</table>
## Results item reduction

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sent (n)</th>
<th>Received (n)</th>
<th>Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>8-12 years</td>
<td>54</td>
<td>51</td>
<td>94%</td>
</tr>
<tr>
<td>13-17 years</td>
<td>51</td>
<td>46</td>
<td>90%</td>
</tr>
<tr>
<td>≥18 years</td>
<td>63</td>
<td>54</td>
<td>86%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age Group</th>
<th>OI Range</th>
<th>OI Cut Off</th>
<th>Selected Items (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8-12 years</td>
<td>0-3.22</td>
<td>≥ 1.57</td>
<td>25</td>
</tr>
<tr>
<td>13-17 years</td>
<td>0-2.89</td>
<td>≥ 1.37</td>
<td>28</td>
</tr>
<tr>
<td>≥18 years</td>
<td>0-3.19</td>
<td>≥ 1.61</td>
<td>29</td>
</tr>
</tbody>
</table>
Striking issues Item Reduction

• The 3 most important items were the same for all age groups

<table>
<thead>
<tr>
<th>Top 3 items in children</th>
<th>%</th>
<th>MI</th>
<th>OI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can eat fewer things</td>
<td>94</td>
<td>3.42</td>
<td>3.22</td>
</tr>
<tr>
<td>Must always watch what you eat</td>
<td>98</td>
<td>3.04</td>
<td>2.98</td>
</tr>
<tr>
<td>The ingredients of a food change</td>
<td>76</td>
<td>3.77</td>
<td>2.88</td>
</tr>
</tbody>
</table>

• Also remarkable differences between age groups
  • curious about forbidden products, only in children
  • carrying Epipen, only in adolescents
  • incomplete food labels, only in adults
Clinical impact

overall importance = item frequency * mean importance

Of each item!
Food Allergy Quality of Life Questionnaire (FAQLQ)

• Self-Administered
• **Adult Form (AF)**
  – ≥ 18 years, 29 items
• **Teenager Form (TF)**
  – 13-17 years, 23 items
• **Child Form (CF)**
  – 8-12 years, 24 items
**Instructions**
The following questions concern the influence your food allergy has on your quality of life. Answer every question by marking the appropriate box with an ‘x’. You may choose from one of the following answers.

0. not  
1. barely  
2. slightly  
3. moderately  
4. quite  
5. very  
6. extremely

<table>
<thead>
<tr>
<th>How troublesome do you find it, because of your food allergy, that you ...</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 must always be alert as to what you are eating?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 are able to eat fewer products?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 are limited as to the products you can buy?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 must read labels?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 have the feeling that you have less control of what you eat when eating out?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 must refuse many things during social activities?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 must disappoint people when they are making an effort to accommodate your food allergy?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 are less able to spontaneously accept an invitation to stay for a meal?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 are less able to taste or try various products when eating out?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 can eat out less?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 must personally check whether you can eat something when eating out?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 hesitate eating a product when you have doubts about it?</td>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8-12 yrs</td>
<td>13-17 yrs</td>
<td>&gt;18 yrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>----------</td>
<td>-----------</td>
<td>---------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patients (n)</strong></td>
<td>80</td>
<td>75</td>
<td>79</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sex, n (m/f)</strong></td>
<td>45/34</td>
<td>34/40</td>
<td>19/60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age, mean in years (SD)</strong></td>
<td>10.2 (SD 1.3)</td>
<td>14.7 (SD 1.3)</td>
<td>37.9 (SD 14.6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>food allergy, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>peanut</td>
<td>60 (75%)</td>
<td>57 (76%)</td>
<td>46 (58%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>tree nut</td>
<td>57 (71%)</td>
<td>56 (75%)</td>
<td>45 (57%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>egg</td>
<td>29 (36%)</td>
<td>26 (35%)</td>
<td>21 (27%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>milk</td>
<td>22 (28%)</td>
<td>30 (40%)</td>
<td>16 (20%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>fish</td>
<td>2 (3%)</td>
<td>13 (16%)</td>
<td>13 (16%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>shell fish</td>
<td>7 (9%)</td>
<td>12 (15%)</td>
<td>14 (18%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>wheat</td>
<td>10 (13%)</td>
<td>5 (7%)</td>
<td>15 (19%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sesame</td>
<td>14 (18%)</td>
<td>8 (11%)</td>
<td>12 (15%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>soy</td>
<td>12 (15%)</td>
<td>17 (23%)</td>
<td>13 (16%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>celery</td>
<td>1 (1%)</td>
<td>3 (4%)</td>
<td>11 (14%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of food allergies, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 food</td>
<td>21 (26%)</td>
<td>12 (16%)</td>
<td>20 (25%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 foods</td>
<td>22 (28%)</td>
<td>31 (41%)</td>
<td>21 (27%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 foods</td>
<td>18 (23%)</td>
<td>8 (11%)</td>
<td>16 (20%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;3 foods</td>
<td>19 (24%)</td>
<td>23 (31%)</td>
<td>22 (28%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Severity of symptoms according to Mueller, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade I</td>
<td>8 (10%)</td>
<td>4 (5%)</td>
<td>4 (5%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade II</td>
<td>14 (18%)</td>
<td>11 (15%)</td>
<td>4 (5%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade III</td>
<td>40 (50%)</td>
<td>39 (52%)</td>
<td>35 (44%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade VI</td>
<td>15 (19%)</td>
<td>17 (23%)</td>
<td>32 (41%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Discriminative ability

**Children (8-12 years)**

- Number of reported food allergies:
  - 1 or 2 FA
  - 3 or more FA

**Adolescents (13-17 years)**

- Number of reported food allergies:
  - 1 FA
  - 2 or more FA

**Adults (18 years and older)**

- Number of reported food allergies:
  - 1 to 3 FA
  - 4 or more FA

**Reported anaphylaxis**

- **Children (8-12 years)**
  - No
  - Yes

- **Adolescents (13-17 years)**
  - No
  - Yes

- **Adults (18 years and older)**
  - No
  - Yes

* p<0.05
Cross-Sectional Validation

- Is the instrument measuring what it is supposed to measure?
- No gold standard
- Construct validity
- Food Allergy Independent Measure (FAIM)
FAIM

• HRQL affected by food allergy
• Independent measure
  – Determinant of QoL
  – Not a QoL item itself
  – Indication of severity of disease
  – Target for intervention
• Perceived expectation
The following four questions concern the chance that you think you have of an event related to your food allergy. You may choose from the following answers. This is followed by two further questions about your food allergy. Answer every question by marking an ‘x’ in the appropriate box.

0. never (0% chance)
1. very small chance
2. small chance
3. fair chance
4. great chance
5. very great chance
6. certain (100% chance)

How great do you think the chance is that you …

<table>
<thead>
<tr>
<th>a. will accidentally eat something to which you are allergic?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>b. will have a severe reaction if you accidentally eat something to which you are allergic?</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>c. will die if you accidentally eat something to which you are allergic?</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>d. can not effectively deal with an allergic reaction should you accidentally eat something to which you are allergic?</td>
</tr>
<tr>
<td>0 1 2 3 4 5 6</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

How many products must you avoid because of your food allergy?

| □ almost none    | □ negligibly small |
| □ very few      | □ very small       |
| □ a few         | □ small            |
| □ some          | □ moderate         |
| □ many          | □ great            |
| □ very many     | □ very great       |
| □ almost all    | □ extremely great  |

How great is the impact of your food allergy on your social life?

□ almost none
□ very few
□ a few
□ some
□ many
□ very many
□ almost all
## Construct validity

<table>
<thead>
<tr>
<th></th>
<th>mean FAIM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total FAQLQ-AF</td>
<td>0.79</td>
</tr>
<tr>
<td>Individual FAQLQ-AF items</td>
<td>0.36-0.70</td>
</tr>
<tr>
<td>Total FAQLQ-TF</td>
<td>0.57</td>
</tr>
<tr>
<td>Individual FAQLQ-TF items</td>
<td>0.17-0.54</td>
</tr>
<tr>
<td>Total FAQLQ-CF</td>
<td>0.61</td>
</tr>
<tr>
<td>Individual FAQLQ-CF items</td>
<td>0.16-0.60</td>
</tr>
</tbody>
</table>

*Spearman’s Correlation Coefficients*
Conclusion cross-sectional validation

- FAQLQs are **valid** and **reliable** to measure the impact of food allergy on quality of life
- FAQLQs measure the most important issues that food allergic patients have to face
- Short and easy to use
- Useful tools in clinical research
Additional methods

- **Internal consistency**: Cronbach’s alpha
- **Test-retest reliability**: Intraclass Correlation Coefficient (ICC)
- **Domain structure**: Factor analysis and expert opinion
- **Discriminative ability**: comparing patients who differ in severity of symptoms and number of food allergies with Mann-Whitney test.
- **Convergent and discriminant validity**:
  - generic QoL questionnaires
  - CHQ-CF87 for children and adolescents
  - RAND-36 for adults
Convergent and discriminant validity

- **FAQLQ-CF** correlated weakly with 8 of the 11 CHQ-CF87 scales (rho 0.29-0.45)
- **FAQLQ-TF** correlated weakly with 6 of the 11 CHQ-CF87 scales (rho 0.29-0.44)
- **FAQLQ-AF** did not correlate with any of the RAND-36 scales
Longitudinal validation and measurement of “impact”

(self-perceived) Food Allergy → FAQLQ baseline (1 month to 1 day before DBPCFC) → DBPCFC → FAQLQ 6-month follow-up
Europrevall

So, are we finished?
After Europrevall – key areas for further development

• (Increasing) prevalence
• Outcome measures
• Financial and intangible (QoL) impact
• **Tools to undertake cost-utility analysis (QALYs)**
• Better understanding of risk factors
• **Primary prevention strategies**
• Standardization of double blind challenge tests
• Increased knowledge of allergens in foods and their significance
• **Simple, accurate diagnosis**
• **Treatment**
• Consumer preferences and dislikes (labeling)
• **Effective prevention of exposure**
After Europrevall – key areas for further development

- Tools to undertake cost-utility analysis (QALYs)
- Primary prevention strategies
- Simple, accurate diagnosis
- Treatment
- Effective prevention of exposure
  - Threshold information
  - Traceability technologies
  - Risk analysis, risk perception
After Europrevall – key areas for further development

- Tools to undertake cost-utility analysis (QALYs)
- Primary prevention strategies
- Simple, accurate diagnosis
- Treatment
- Effective prevention of exposure
  - Threshold information
  - Traceability technologies
  - Risk analysis, risk perception