The concept of thresholds:
do safe doses exist for food-allergic patients?

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Murdoch Childrens Research Institute
Royal Children’s Hospital
University of Melbourne
Talk overview

• What type of allergen labelling is there?
• How widespread is the use of precautionary labelling?
• How do consumers interpret precautionary labelling?
• How unsafe are consumer behaviours?
• How is industry responding to growing concerns about consumer complacency towards labels?
• What should we advise our patients?
Talk overview

- **What type** of allergen labelling is there?
  - Mandatory
    - Most countries have food labelling legislation for added ingredients
  - Precautionary (voluntary)
    - no current legislation (for eg “may contain”)
    - except in Japan and Switzerland where precautionary labelling is banned
# International comparison of mandatory declarations on processed foods

<table>
<thead>
<tr>
<th>Country</th>
<th>Peanuts</th>
<th>Tree nuts</th>
<th>Egg</th>
<th>Milk</th>
<th>Fish</th>
<th>Crustaceans</th>
<th>Sesame</th>
<th>Soy</th>
<th>Cereals</th>
<th>Celery</th>
<th>Mustard</th>
<th>Sulphites</th>
<th>Lupin</th>
<th>Molluscs</th>
<th>Buckwheat</th>
<th>Shrimp</th>
<th>Crap</th>
<th>Wheat</th>
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<td>Japan</td>
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</table>

*Sourced from The Institute of Food Science & Technology UK*
Talk overview

• What **type** of allergen labelling is there?
• How **widespread** is the use of precautionary labelling?
<table>
<thead>
<tr>
<th>Category of food</th>
<th>Number (%) of products with an advisory statement*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Peanut</td>
</tr>
<tr>
<td>Sweet biscuits (n = 130)</td>
<td>117 (93%)</td>
</tr>
<tr>
<td>Chocolates (n = 60)</td>
<td>43 (80%)</td>
</tr>
<tr>
<td>Bakery items (eg, cakes) (n = 35)</td>
<td>24 (71%)</td>
</tr>
<tr>
<td>Muesli bars and snack bars (n = 27)</td>
<td>13 (67%)</td>
</tr>
<tr>
<td>Dinner bases and stocks (n = 32)</td>
<td>19 (59%)</td>
</tr>
<tr>
<td>Savoury biscuits (n = 41)</td>
<td>23 (56%)</td>
</tr>
<tr>
<td>Lollies (n = 55)</td>
<td>29 (56%)</td>
</tr>
<tr>
<td>Breakfast cereals (n = 63)</td>
<td>25 (41%)</td>
</tr>
<tr>
<td>Instant noodles (n = 18)</td>
<td>7 (39%)</td>
</tr>
<tr>
<td>Pasta sauces (n = 15)</td>
<td>5 (33%)</td>
</tr>
<tr>
<td>Bread (n = 16)</td>
<td>5 (31%)</td>
</tr>
<tr>
<td>Soups (n = 20)</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>Cake mixes (n = 30)</td>
<td>4 (13%)</td>
</tr>
<tr>
<td>Tinned meals (n = 17)</td>
<td>2 (12%)</td>
</tr>
<tr>
<td>Baby foods (n = 30)</td>
<td>3 (10%)</td>
</tr>
<tr>
<td>Pasta (n = 13)</td>
<td>0</td>
</tr>
<tr>
<td>Chips (n = 20)</td>
<td>0</td>
</tr>
<tr>
<td>Other (eg, tinned fish, breadcrumbs, sauces, custard powder) (n = 139)</td>
<td>26 (19%)</td>
</tr>
</tbody>
</table>

* Number of products that had an advisory statement but did not have the allergen of interest listed as an ingredient. The denominators used to calculate percentages were the numbers of products within each category of food that did not have the allergen of interest listed as an ingredient.
Talk overview

• What type of allergen labelling is there?
• How widespread is the use of precautionary labelling?
• How do consumers interpret precautionary labelling?
Perceptions of precautionary labelling among parents of children with food allergy and anaphylaxis

1. Behaviour relating to food labels among parents of food-allergic children with a history of anaphylaxis (113) and with a history of mild to moderate IgE-mediated reactions (133)

<table>
<thead>
<tr>
<th>Question and possible responses</th>
<th>Anaphylaxis</th>
<th>Mild–moderate reactions</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>If your child has a specific food allergy (e.g., peanuts) do you intentionally remove food products containing the specific food from the house?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>39 (35%)</td>
<td>65 (49%)</td>
<td>0.04</td>
</tr>
<tr>
<td>Not sure</td>
<td>1 (1%)</td>
<td>3 (2%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>73 (55%)</td>
<td>64 (48%)</td>
<td></td>
</tr>
<tr>
<td>When you buy a food product which part of the label do you check for an allergen?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingredients only</td>
<td>27 (24%)</td>
<td>32 (25%)</td>
<td></td>
</tr>
<tr>
<td>Precautionary information only</td>
<td>1 (1%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Both</td>
<td>82 (73%)</td>
<td>95 (74%)</td>
<td></td>
</tr>
<tr>
<td>Neither</td>
<td>2 (2%)</td>
<td>1 (1%)</td>
<td>0.88</td>
</tr>
<tr>
<td>Would you give your child a food if the food he or she was allergic to was listed in the precautionary labelling section?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>64 (58%)</td>
<td>81 (62%)</td>
<td></td>
</tr>
<tr>
<td>Not sure</td>
<td>8 (7%)</td>
<td>11 (8%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>38 (35%)</td>
<td>39 (30%)</td>
<td>0.72</td>
</tr>
<tr>
<td>How often do you look at precautionary food labels?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Only when I buy a product for the first time</td>
<td>33 (30%)</td>
<td>44 (34%)</td>
<td></td>
</tr>
<tr>
<td>Only occasionally when I buy a product</td>
<td>10 (9%)</td>
<td>14 (11%)</td>
<td></td>
</tr>
<tr>
<td>Most of the times when I buy a product</td>
<td>31 (28%)</td>
<td>34 (26%)</td>
<td></td>
</tr>
<tr>
<td>Every time I buy a product</td>
<td>36 (33%)</td>
<td>38 (29%)</td>
<td>0.85</td>
</tr>
</tbody>
</table>
Parent survey (n=298) of which labels indicate that they would avoid the food for their food allergic child.
Talk overview

• What type of allergen labelling is there?
• How widespread is the use of precautionary labelling?
• How do consumers interpret precautionary labelling?
• How unsafe are consumer behaviours?
To assess the risks taken by allergic consumers ignoring precautionary labelling:

- Examined the level of cross contamination for peanut, hazelnut, milk, egg, soy and lupin
- Chose 5 high-risk snack product categories from each of the 3 main supermarket chains

Zurzolo et al JACI in Practice 2013
<table>
<thead>
<tr>
<th>Chocolate</th>
<th>Breakfast cereal</th>
<th>Muesli bars</th>
<th>Savoury biscuits</th>
<th>Sweet biscuits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dark chocolate block</td>
<td>Corn flakes</td>
<td>Choc coated honey comb &amp; nut muesli bar.</td>
<td>Cracker plain round</td>
<td>Mint slice chocolate biscuits</td>
</tr>
<tr>
<td>Hazelnut chocolate block</td>
<td>Rice pops</td>
<td>Yoghurt strawberry muesli bar</td>
<td>Cracker chicken</td>
<td>Chocolate biscuits fruit &amp; nut</td>
</tr>
<tr>
<td>Milk chocolate block</td>
<td>Wheat biscuit</td>
<td>Choc swirl muesli bar</td>
<td>Rice cakes</td>
<td>Rocky road chocolate biscuit</td>
</tr>
<tr>
<td>3 batches*</td>
<td>3 batches*</td>
<td>3 batches*</td>
<td>3 batches*</td>
<td>3 batches*</td>
</tr>
<tr>
<td>ELISA Cow’s milk Egg Peanut Hazelnut Soy Lupin</td>
<td>ELISA Cow’s milk Egg Peanut Hazelnut Soy Lupin</td>
<td>ELISA Cow’s milk Egg Peanut Hazelnut Soy Lupin</td>
<td>ELISA Cow’s milk Egg Peanut Hazelnut Soy Lupin</td>
<td>ELISA Cow’s milk Egg Peanut Hazelnut Soy Lupin</td>
</tr>
</tbody>
</table>
• In total 128 processed foods with precautionary statements were examined

• ELISA testing undertaken by FACTA, Australia
  » peanut, hazelnut, milk, egg, soy and lupin

• Laboratory blinded to food label and supermarket origin

Zurzolo et al JACI in Practice 2013
Talk overview

• What type of allergen labelling is there?
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• How is industry responding to growing concerns about consumer complacency towards labels?
US FDA Allergen Thresholds

- Threshold Working Group Report (March, 2006)
- “Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food”
  
  *Journal of Food Protection, 2008 71;5:1043–1088*
US FDA Conclusion

Conclusion: Finding 4

• “the quantitative risk assessment-based approach provides the strongest, most transparent scientific analyses........

• However, . . the currently available data are not sufficient ......

• A research program should be initiated to develop applicable risk assessment tools”
Voluntary Incidental Trace Allergen Labelling (VITAL)

- initiative from food industry;
- established by Allergen Bureau in 2007
- voluntary program
- aimed to limit overuse or misuse of precautionary labelling used increasingly by industry in the absence of regulatory thresholds to convey possible risk from shared equipment, shared facilities, and ingredient co-mingling
Initial VITAL action levels were based on:

- minimum provoking doses for regulated allergenic foods
  - collated by the 2006 U.S. Food & Drug Administration (FDA) Threshold Working Group
  - 10-fold uncertainty factor applied because based on limited data
- assumption of a consumption amount of 5 gm
Voluntary incidental trace allergen labelling (VITAL)

- Used **new** precautionary statement
  
  “may be present”
**Table 3** Prevalence of different types of precautionary labelling among the 1355 products examined

<table>
<thead>
<tr>
<th>Categories</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No statement</td>
<td>473</td>
<td>(35.0%)</td>
</tr>
<tr>
<td>May contain traces of</td>
<td>392</td>
<td>(29.0%)</td>
</tr>
<tr>
<td>May be present (statement used in VITAL process)</td>
<td>172</td>
<td>(12.7%)</td>
</tr>
<tr>
<td>Made on the same production line</td>
<td>164</td>
<td>(12.1%)</td>
</tr>
<tr>
<td>Made in the same factory</td>
<td>99</td>
<td>(7.3%)</td>
</tr>
<tr>
<td>Allergen free</td>
<td>44</td>
<td>(3.2%)</td>
</tr>
<tr>
<td>Made on the same equipment</td>
<td>11</td>
<td>(0.8%)</td>
</tr>
<tr>
<td>Total with any precautionary statements:</td>
<td>882</td>
<td>(65.0%)</td>
</tr>
</tbody>
</table>

Type of precautionary labelling (among 882 products with any labelling)

<table>
<thead>
<tr>
<th>Categories</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VITAL (‘May be present’)</td>
<td>172</td>
<td>(19.5%)</td>
</tr>
<tr>
<td>Any other statements</td>
<td>710</td>
<td>(80.5%)</td>
</tr>
</tbody>
</table>

VITAL, Voluntary Incidental Trace Allergen Labelling.
VITAL 2.0 Grid Revision

• Australian Allergen Bureau Management Committee and Food Allergy Research & Resource Program (FARRP) collaborated to assemble a Scientific Expert Panel to consider revision of Grid Action Levels

• Panelists: Steve Taylor, FARRP
  Joe Baumert, FARRP
  Rene Crevel, Unilever
  Geert Houben, TNO
  Simon Brooke-Taylor, consultant
  Katie Allen, Royal Children’s Hospital

• Assistance provided by: Ben Remington (FARRP), Astrid Kruizinga (TNO), Ellen Dutman (TNO), and Harrie Buist (TNO)
VITAL 2.0 Grid Revision

• Focused on data from all commonly allergenic foods on priority lists in Australia, U.S. and Europe

• Available data were gleaned from published literature where possible and unpublished clinical data were also used from Dutch clinics and FARRP studies
  • Double blind placebo challenge controlled studies for age 3.5yrs, open accepted for age <3.5 years
  • Dose at which first objective sign obtained included
VITAL Dataset Progress

Assembled and evaluated clinical data on all possible priority allergenic foods

- Peanut
- Milk
- Egg
- Hazelnut
- Soybean
- Wheat
- Cashew
- Mustard
- Lupine
- Sesame seed
- Shrimp
- Celery
- Fish
• Used statistical dose-distribution modelling (both discrete and cumulative doses) and applied 3 different models: log-normal, log-logistic, and Weibull to all data sets

• Determined NOAELs and LOAELs for individual subjects in studies and used interval-censoring survival analysis to estimate thresholds

• Reference values determined from ED01
  — or 95% lower confidence interval of ED05 for some less common allergens
  • In the past extensively hydrolysed thresholds of reactivity were set at ED10
  • Evidence from dataset that mild reactions predominate at ED01
  • For peanut for ED01 predicted to be 25 fold lower than ED for anaphylaxis
Log-Normal Population Distribution (expressed as whole peanut)
Factors assessed that might be expected to influence threshold development

Challenge data:
Age of participants – children vs adults
Geographical differences impacting on challenge data
Different clinic practices
Form of allergen used – eg liquid vs particulate

Consumer behaviour:
Amount ingested in a routine serving
Peanut by Dose Material

ED$_{05}$ Values (mg peanut protein)
- Ground Peanut: 2.1 mg
- Peanut Flour: 1.4 mg
Milk by Dose Material

ED$_{05}$ Values (mg milk protein)
- Liquid Milk: 1.9 mg
- NFDM: 2.7 mg
ED$_{05}$ Values (mg egg protein)

Cooked Whole Egg: 4.7 mg
Raw Whole Egg: 3.4 mg
Raw Egg White: 0.2 mg
## VITAL 2.0 Scientific Expert Panel Recommendations (ED01)

<table>
<thead>
<tr>
<th>Allergen</th>
<th>mg Protein Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanut</td>
<td>0.2</td>
</tr>
<tr>
<td>Milk</td>
<td>0.1</td>
</tr>
<tr>
<td>Egg</td>
<td>0.03</td>
</tr>
<tr>
<td>Hazelnut</td>
<td>0.1</td>
</tr>
<tr>
<td>Soy</td>
<td>1.0</td>
</tr>
<tr>
<td>Wheat</td>
<td>1.0</td>
</tr>
<tr>
<td>Cashew</td>
<td>2.0</td>
</tr>
<tr>
<td>Mustard</td>
<td>0.05</td>
</tr>
<tr>
<td>Lupin</td>
<td>4.0</td>
</tr>
<tr>
<td>Sesame</td>
<td>0.2</td>
</tr>
<tr>
<td>Shrimp</td>
<td>10.0</td>
</tr>
<tr>
<td>Celery</td>
<td>n/a</td>
</tr>
<tr>
<td>Fish</td>
<td>n/a</td>
</tr>
</tbody>
</table>

KJ Allen *et al*, Allergen reference doses for precautionary labelling (VITAL 2.0): clinical implications. JACI 2013 *in press*
VITAL 2.0

• Publications outlining new reference doses:
  – Allen et al, Allergen reference doses for precautionary labeling (VITAL 2.0): clinical implications JACI 2013
  – Taylor et al Establishment doses for residues of allergenic foods: report of the VITAL expert panel 2014

• Feb 2013 – Single-Dose Peanut Challenge Trial in Ireland (Hourihane), Australia (Allen) and USA (Shreffler) to validate the predicted ED05 – FAARP (Taylor) sponsored
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• What should we advise our patients?
Historical Approach to Precautionary labelling

• Physicians recommended complete avoidance (ZERO threshold)
• impossible to achieve
“These statements are used by manufacturers to indicate that the product may be contaminated with peanut through processing and packaging. At present these statements are voluntary and there are no clear guidelines for companies regarding how and when to use them.

Department of Allergy, Royal Children’s Hospital
Vicki McWilliam and Mimi Tang
• “These statements are used by manufacturers to indicate that the product may be contaminated with peanut through processing and packaging. At present these statements are voluntary and there are no clear guidelines for companies regarding how and when to use them.

• The wording of the statements makes it very difficult to determine your level of risk and a product that does not contain the statement may be no safer than a product that does.
• “These statements are used by manufacturers to indicate that the product may be contaminated with peanut through processing and packaging. At present these statements are voluntary and there are no clear guidelines for companies regarding how and when to use them.

• The wording of the statements makes it very difficult to determine your level of risk and a product that does not contain the statement may be no safer than a product that does.

• The chances of having a significant allergic reaction through contamination during processing are extremely unlikely.

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• The wording of the statements makes it very difficult to determine your level of risk and a product that does not contain the statement may be no safer than a product that does.

• The chances of having a significant allergic reaction through contamination during processing are extremely unlikely.

• People with severe or anaphylactic reactions should use these products with caution.
“These statements are used by manufacturers to indicate that the product may be contaminated with peanut through processing and packaging. At present these statements are voluntary and there are no clear guidelines for companies regarding how and when to use them.

- The wording of the statements makes it very difficult to determine your level of risk and a product that does not contain the statement may be no safer than a product that does.
- The chances of having a significant allergic reaction through contamination during processing are extremely unlikely.
- People with severe or anaphylactic reactions should use these products with caution.
- The only safe alternative is extremely limiting as it would be to not include any commercial food products in your child’s diet.

Department of Allergy, Royal Children’s Hospital
Vicki McWilliam and Mimi Tang
• “These statements are used by manufacturers to indicate that the product may be contaminated with peanut through processing and packaging. At present these statements are voluntary and there are no clear guidelines for companies regarding how and when to use them.

• The wording of the statements makes it very difficult to determine your level of risk and a product that does not contain the statement may be no safer than a product that does.

• The chances of having a significant allergic reaction through contamination during processing are extremely unlikely.

• People with severe or anaphylactic reactions should use these products with caution.

• The only safe alternative is extremely limiting as it would be to not include any commercial food products in your child’s diet.

• For children with severe allergic reactions companies can be contacted directly to explore food processing, packaging and cleaning procedures”

Department of Allergy, Royal Children’s Hospital
Vicki McWilliam and Mimi Tang
The value of precautionary labelling

• Should be simple to understand
• Indicate a level of risk
• Visible
• Reliable
• Safe
Products WITH precautionary labelling

*Products with PAL (65% of supermarket products)*

- VITAL risk assessment. Uses "may contain: x" statement.
- Higher risk of allergic reaction.
- Use or type of evaluation unknown. Uses any one of over 10 PAL statements.
- Unknown risk of allergic reaction.

- Consumers don't know how to interpret
- Health care professionals don't know what to advise
- Consumers don't know how to interpret
- Health care professionals don't know what to advise
Products WITHOUT precautionary labelling

Products without PAL
(35% of supermarket products)

VITAL risk assessment. No statement used.

Low risk of reaction.

Use or type of evaluation unknown. No statement used.

Unknown risk of allergic reaction.

Consumers can't tell these products apart.

Consumers can't tell these products apart.
Conclusions

• Precautionary labeling is prevalent, ambiguous and often ignored
Precautionary labelling only informs patient about what to avoid

**Permissive labelling urgently required** to inform patient about what food they can eat

No manufacture is indicating which food has been through a risk assessment tool (eg “VITALISED”)

**VITALISED foods** should be safer – but the patient has no idea which these foods are

Conclusions
Precautionary labelling of foods for allergen content: are we ready for a global framework?

Katrina J Allen¹,²,³+, Paul J Turner⁴,⁵+, Ruby Pawankar⁶*, Stephen Taylor⁷, Scott Sicherer⁸, Gideon Lack⁹,¹⁰, Nelson Rosario¹¹, Motohiro Ebisawa¹², Gary Wong¹³, E N Clare Mills³, Kirsten Beyer¹⁴, Alessandro Fiocchi¹⁵ and Hugh A Sampson⁸
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