Translation to risk management
The health practitioners’ perspective

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Levels of Acceptable Risk

Food allergy: Stakeholder perspectives on acceptable risk

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“For consumers with food allergy, effective avoidance is confusing and requires enormous lifestyle upheaval. For industry, prevention of allergen contamination is costly and currently lacks scientific and government guidance.”

SL Taylor 2010

…but where does the health care professional fit into this?
Objectives

• The role of the HCP is to advise their individual allergic patients on how to effectively and confidently manage their food allergy
• The adoption of the agreed reference doses for allergen:
  – may facilitate the adoption of a consistent management approach
  – may lead to tailored advice for the individual patient (patients sensitivity/individual risk assessment)
Concerns of HCPs that I have quizzed over the past few weeks

1) Can we trust the so-called threshold levels?

“Current knowledge does not enable the risk to the individual patient of (severe) reactions to be estimated with sufficient accuracy in a quantitative or qualitative form. This currently precludes meaningful discussion of a defined acceptable level of risk for most food-allergic patients. There may be an exception for patients reacting very mildly to high doses in food challenge tests and who are possibly in the process of outgrowing their food allergy”

Madsen et al. 2010

We have heard yesterday about all the factors that can affect threshold levels...
Concerns of Health Care Practitioners

- Exercise
- Hormone levels
- Stress
- Infections
- Medication
- Matrix
- Season
- IgE profile/SPT size

ED01/ED05?
Concerns of HPCs

2) Can we trust the food industry’s tests?

- In the US: Detectable residues of allergenic food in 5.3% of advisory-labelled products and 1.9% of similar products without advisory statements.
- In this study <1% of products would contain more than 3.6 mg peanut (considered safe for 95% of peanut allergic individuals).
- “We must emphasize that we analysed only 1 sample per product and thus cannot exclude the possibility that other samples of the same product might have contained higher levels.”

Taylor SL 2010

*It all depends which bit of the chocolate you mix up, where you stick the electrode in and how the electrode measures…*

Julie Nordlee 2009
Can we trust the food industry’s tests

• In Europe: 315 cookies analysed, 25 % contained traces of hazelnuts and 23 % traces of peanuts. Of the 254 chocolates analysed, 75 % of the products contained traces of hazelnuts and 37 % contained traces of peanuts.

• The majority of food products did not declare the allergen in question in the main ingredient list; however, most contained a precautionary statement.  

Pele et al. 2007
How to confidently manage food allergies
Advising patients

• Will it improve clinical outcomes?
  – Food challenges to individual nuts are a huge burden on the health service, but performed to improve patient outcomes...but
  – Risk taking behaviour is the same in children who are told to avoid all nuts or only those nuts allergic to
  – Up to 50% did avoid “may contain” statements

• Also absence of data to indicate if this risk taking behaviour leads to reactions more often

Brown et al. 2012
Advising patients

• Will we understand the labelling?
  – I am still confused about the foods exempted from the allergen labelling rules

So in order to advise patients

• HCPs need training!
• Understand food processing, testing for allergens and food labels
  – Many HCPs do not understand the methods of food processing and the risk of contamination involved
  – Many HCPs do not understand techniques used and limitations of these when testing for allergens in foods
The particular role of the dietitian

Testing the VITAL labelling “principle” in clinic...

– What if my child/I eat 2-3 products within the allowed action levels and push themselves over the limit?
– Will my child/I react and how severe will the reaction be?
…and I do...

…but now I have somewhat of a better idea…
## Knowledge comparison of dietitians in Aus, US and UK (%)

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<th>Task</th>
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<th>MODERATE</th>
<th>LOW</th>
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<td>Develop Food Challenge protocols</td>
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<td>Educate patients on avoidance</td>
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<td>Develop elimination diet</td>
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<td>Manage Feeding problems</td>
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</table>
Educating the patient

• Foods to avoid
  – Will they take any notice of what we say?
  – Up to 50% of patients do not avoid “may contain” labelling
    Noimark et al. 2009 and Cornelisse-Vermaat et al. 2008

• Food to include
  – Will it expand the range of foods that they can eat?
    • In Australia: Up to 50% of products contain “may contain” warnings
      Koplin et al. 2010
    • In the UK: Up to 56% of products contain “may contain” warnings
      FSA 2002

• Nutritional adequacy?
Parent’s expectations and feedback regarding a dietetic consultation

- A health professional that provides reassurance
- A teacher to provide the necessary knowledge
- Providing hints and tips
- Supporting parents
- My advocate – who fights my corner
- Let me know I am not on my own

Mackenzie and Venter Submitted for publication

THIS PUTS A REAL BURDEN ON US TO MAKE SURE THE INFORMATION WE PROVIDE IS CORRECT AND SAFE
The adoption of the agreed reference doses for allergens may facilitate the adoption of a consistent management approach.
Providing a consistent management approach

In 2009...

or “produced on same line as products containing peanut…”, which imply that risk may vary accordingly. It cannot yet be said confidently that these labelling options are reassuring or even accurate as labelling strategies can always be defeated or undermined by human error.

**Conclusion**

At the present time physicians are unable to stratify risk for any *individual* patient, so the advice they give to *all* peanut allergic patients must be to accept advisory label and to industry and regulators to ensure the information on the labels is meaningful, reasonable and reliable.

Jonathan O'B. Hourihane
3.14.09

In 2012...

_topic of many debates at food allergy conferences during 2012/2013_

...are we going to have the same debates about…”may be present”...

...
The adoption of the agreed reference doses for allergens may lead to tailored advice for the individual patient (patients sensitivity/individual risk assessment)
...we may now end up having to set two levels of risk assessment

- ...the 1-5% of patients who will react to lower levels of allergen than the action levels set

- ...patients that should be “allowed” to eat may be present
Identifying those at risk..

- Physicians regard risk as acceptable only if measures aimed at reducing the risk do more harm than good.

- *Estimates of acceptable risk are largely subjective.*

Madsen et al. 2010
• The severity of a reaction cannot be accurately predicted by the severity of past reactions or by the sIgE levels or size of a skin prick test (SPT) wheal.

• Although reactions after a severe reaction are also likely to be severe, mild reactions can also be followed by more severe reactions.
From this morning sessions..

- The action levels will not protect ONE particular individual
- BUT increase the safety of those suffering from food allergy...
- Although zero reactions is not an achievable goal...
• Is it possible to define an acceptable risk to increase food choice in “mild” reactors or those wanting to take more risks?

• Would only be possible if one could quantify and qualify the risk (of severe) reactions in the individual patient i.e.
  • how great (or small) is the chance that the patient will react if he/she takes a certain amount of a certain allergenic food?
  • .....if the patient reacts, how severe will the reaction be?

Madsen et al. 2010
So what we do clinically – NICE...

Asthma
- Remote areas
- Infection
- Stress
- Anaphylaxis in past
- Reacted to small amounts in the past
- Poor adherence to other treatment

Infection
- Alcohol
- Exercise
- Multiple food allergies
- Limited understanding

Remote areas

Stress

Anaphylaxis in past

Reacted to small amounts in the past

Poor adherence to other treatment

Limited understanding
Identify the dose that poses a risk?

• Zero risk is not a possibility

• Is LOEAL good enough for our patients?

• But then again... is current labelling good enough – anyway?
In summary

• HCPs agree that we need a better labelling system

• We are concerned about those highest at risk and how to identify them

• We need “some” reassurance that we can trust the tests used to detect allergens in food

• We need training to understand any new labelling initiative in order to educate our patients

• We do not want to lose the trust of our patients