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A survey of anaphylaxis to packaged foods in Australasia.  
Original article

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**What is already known about this topic?**

- Anaphylaxis to packaged foods, where the suspected trigger food is not a listed ingredient is unknown.
- As PAL labelling is currently voluntary (with some but not all packaged foods labelled with a variety of advisory warnings)
- There is no effective way to currently determine whether or not an unlabelled product (foods without PAL) is safe for consumption by the food allergic community.

**What this paper adds?**

- Anaphylaxis to packaged foods where the suspected trigger food is not a listed ingredient, is not a rare occurrence, with peanut being the most common suspected contaminating allergen in Australasia
- Current precautionary allergen labelling practices do not assist consumers in selecting foods which are safe for consumption.

## Aims

To examine reports of anaphylaxis in Australasia from consumption of packaged food products with or without PAL, where the known allergen triggers **were not** a listed ingredient.

## Methods

A questionnaire to all members of the Australasian Society of Clinical Immunology and Allergy (N=548). Participants were asked to complete a survey reporting whether they have had seen any patients over the last 3 months reporting anaphylaxis following ingestion of a packaged food where the suspected food allergen was not a listed ingredient

## Results

Of the n=548 members approached n=198 responded (response rate 36.1%). There were 14 reports of anaphylaxis to packaged foods (where the suspected allergen was not a listed ingredient) which met the case definition from a total of 198 respondents over the 9 month period. Of those reactions 50.0% (CI 95% 21-78) were reported from foods which did not have a PAL statement and 50.0% (CI 95% 21-78) were due to peanut.

## Conclusion

Anaphylaxis to undeclared allergens was not rare and did not appear to depend on whether the product was labelled with precautionary advice. There is currently no reliable labelling system which can inform food allergic consumers in safer food choices. Improvements in the regulation of food labelling with PAL are required

## Key words

Precautionary Allergen Labelling (PAL), Voluntary Incidental Trace Allergen Labelling (VITAL), Food Allergy, Anaphylaxis

## Abbreviations

Precautionary Allergen Labelling (PAL), Voluntary Incidental Trace Allergen Labelling (VITAL)

## Introduction

IgE mediated food allergy in Australia is common and Australia has the highest reported prevalence rates in the world. Hospital admissions for food-related anaphylaxis have increased in Australia and the USA <sup>[1-3]</sup>. With no established cure to date, the food allergic community must rely on abstinence from the offending food. In order to achieve this, the food allergic consumer relies on food labels. **Anaphylaxis is a potentially life-threatening systemic allergic reaction that has a rapid onset that can also be fatal <sup>[4]</sup>. Motosue et al. 2016 showed that from the period of 2005 through to 2014 the rate of food-related anaphylaxis increased by 124% in emergency departments within the United States <sup>[2]</sup>. Similarly Mullins et al. (2015) examined hospital admissions for anaphylaxis in Australia between 2005-2006 and 2011-2012 and compared their findings to previous published prevalence data. Their result showed that food-related anaphylaxis has increased in all age groups examined by a 1.5-fold increase over 7 years <sup>[3]</sup>.**

Precautionary allergen labelling (PAL) is the practice of including statements on food products about the possible presence of allergens (such as 'may contain traces of XXX'). There is no standardized, uniform wording or regulation for PAL- although its use by the food industry is widespread. We have previously reported that 65% of packaged goods within a supermarket setting contain a PAL statement <sup>[5]</sup>. The abundance and ambiguous nature of these statements makes it very difficult for the food allergic consumer to avoid these foods. We have shown that consumers and health professionals are confused by PAL and as a consequence may disregard PAL statements altogether <sup>[6, 7]</sup>. The magnitude of the problem and how frequently anaphylaxis results from consumption of food products that do not list known trigger allergens as ingredients is unknown. **The presence of undisclosed allergens in food is ubiquitous. Major allergens have been found in packaged food products with or without precautionary labelling <sup>[8, 9]</sup>.** Therefore we aimed to investigate reports of new cases of anaphylaxis from packaged food products where the reaction was due to presumed allergen contamination (not to a listed ingredient) by surveying health professionals (HP) who most frequently care for patients with anaphylaxis in Australasia.

## Materials and Methods

A questionnaire (on line resource) was distributed to all members (548, 93% of members see patients) of the Australasian Society of Clinical Immunology and Allergy (ASCIA) over a 9 month period (from February -October 2016). ASCIA is the peak professional body of Immunology and Allergy in Australia and New Zealand. ASCIA sends out a monthly e-newsletter to its members. Each month over the 9-month study period, the newsletter contained instructions on how to access and complete the survey. Participants were asked to indicate whether or not they had seen a patient reporting anaphylaxis following ingestion of a packaged food. Where the suspected food allergen was not a listed ingredient within the last 3 months and to complete the questionnaire where a report was made. **We used responses from Q3, Q12-13 and Q15 in the HP survey to determine whether the report of anaphylaxis was eligible for inclusion (on line resource).** Steps were taken to avoid duplicated reports by HPs for the same event by checking the reported cases date of birth, date of reaction and trigger food to ensure that it was not previously reported. At the end of the study period, all members were re-surveyed with a simple “Yes” or “No” question to indicate whether they had seen a patient over the past 9 months who they suspected had anaphylaxis to packaged food where the likely allergen was not a listed ingredient.

### Definitions

Reports of anaphylaxis or allergic reactions to packaged foods where the suspected culprit allergen was a listed ingredient were excluded.

For case inclusion anaphylaxis was defined as one or more of the following reported symptoms: difficult/noisy breathing, swelling of tongue, swelling/tightness in throat, difficulty talking and/or hoarse voice, chest tightness and shortness of breath, wheeze or persistent cough, persistent dizziness and/or collapse, or pale and floppy as part of a generalized allergic reaction (in young children only). Healthcare providers (HP) were defined as any member of ASCIA which included allergy/immunology specialist, trainee allergy and immunology specialist, other medical practitioners, nurses and dietitians.

### Statistical analysis

Questionnaire responses were analysed quantitatively and percentages and 95% confidence intervals were calculated in Stata (Stata Corp 2011. Stata Statistical Software Release 12 College Station TX: StataCorp). Ethics was granted by the Royal Children’s Hospital Melbourne, Australia (HREC: 36051A).

## Results

A total of 198 responses were received over the study period, (87 from the initial questionnaire and 111 when resurveyed) which represented 36.1% of the ASCIA membership (Figure 1). Responses were HPs that responded either yes or no to seeing patients that had experienced anaphylaxis to packaged food. There were 14 reports of anaphylaxis 7.1% (95% CI 3.9-11.5) from healthcare providers where sufficient information was provided to meet the study inclusion criteria (six-allergy nurse practitioners; five-pediatric allergists, two adult allergists and one general physician). A further 12 HPs reported possible cases, but there was insufficient information to confirm anaphylaxis, and these cases were excluded.

The age of patients reported ranged from 3 to 63 years (median 12). Eight were female and six were male. Allergy to peanut was the most common known pre-existing food allergy amongst patients (n=10, 71%) followed by milk six, (42%), egg, tree-nuts five, (35%) respectfully and six (43%) had multiple food allergies (Table 1). The suspected food trigger/s for the reported episode of anaphylaxis were peanut six, tree nuts four, cow's milk four, egg one and unknown one (two people reported 2 trigger foods.)

All individuals were reported to have symptoms of anaphylaxis on exposure to the packaged food in question (as per the case definition). Wheeze and/or persistent cough (n=10) and swelling/tightness in throat (n=10) were the most common symptoms reported. Six patients reported vocal hoarseness, five reported shortness of breath/difficulty breathing and three reported tongue swelling. Other associated symptoms included urticaria (seven), abdominal pain (seven) and angioedema, (five, Figure 2). Nine (64%) reported reactions occurring within five minutes, three (21%) within 30 minutes and one (7%) within 1 hour. Seven (50%) of individuals reported that 2 - 5 bites of the offending packaged food was consumed before the onset of the allergic reaction, four (28%) consumed most of the serving and in two cases no details were available on timing of reaction. Eleven patients self-administered or were treated with epinephrine. Six (46%) of patients were treated with a combination of epinephrine, antihistamines and steroids, five (38%) were treated with epinephrine only and two (15%) received only antihistamines (one responder did not report on the type of treatment that the patients had received).

12 of the 14 HPs who reported anaphylaxis also indicated whether a PAL statement was present on the packaged food. Of these; six patients reported to the HP that no PAL statement

was present on the packaged food, four reported that the PAL statement specified the suspected trigger food, two reported that the PAL statement did not specify the trigger food and in two cases no PAL information was reported (Figure 3).



## Discussion

Over a 9 month period 14 patients were reported to have experienced convincing anaphylaxis (by history) to packaged food as a result of likely allergen contamination, of which half were to products which did not have PAL. Of the HPs who responded to the survey, 7% reported a case which met our inclusion criteria, which suggests that anaphylaxis to undeclared allergen in Australasia is not rare. A further 12 cases were reported with insufficient detail to confirm or refute that anaphylaxis had occurred.

A strength of the study is that we relied on doctor confirmation of the history of anaphylaxis and not self-reported reactions, which can overestimate incidence. We were interested in anaphylaxis rather than other milder allergic reactions, as we considered that these were potentially life threatening events, likely to be recalled and reported to HP. Milder allergic reactions would have been significantly harder to substantiate by history alone, and less likely to be recalled and reported. However it is likely that we only captured a small proportion of such events across the community, as many patients may not report even severe allergic events at all, or report to their local family practitioner or emergency department, rather than to a HP active in management of patients with allergic disease. We used the ASCIA definition of anaphylaxis, which is well accepted in Australia, but is narrower than some other internationally recognised definitions, such as those of the WAO or AAAAI -which include systemic symptoms in any 2 systems- rather than requiring at least one symptom to include the respiratory tract or cardiovascular system. Similar surveys outside Australia could therefore result in higher frequency of reports of anaphylaxis to packaged foods, based upon variations in definition. Only 36% of the ASCIA membership responded to the survey, and although many members are not in active allergy practice (immunologists, pathologists) it is likely that the number of cases identified underrepresents the total burden of disease. Furthermore we were unable to substantiate the reports by laboratory analysis of the packaged food in question.

That reports of anaphylaxis included reactions to products both with and without PAL is of concern. Allergen contamination in packaged food is not rare, and our results are consistent with studies, which have examined products for allergen contamination. For example, in the USA Ford et al. 2010 examined the frequency and level of contamination of products with and without PAL for egg milk and egg contamination. The author's results showed residues

of allergenic food in 5.3% of PAL products and 1.9% of products without PAL <sup>[9]</sup>. From 2009–2014 43.4% of US food product recalls were related to undeclared allergens. The most frequently reported food types were cookies, muffins, and cakes with the major allergen being egg, milk peanut and tree nuts. A large amount of these recalls were caused by the product not being placed in the correct package. <sup>[10]</sup>. In the UK, a recent report investigated the risk of an allergic reaction within the milk, wheat, hazelnut and peanut-allergic populations both with and without PAL. There were detectable levels of common allergens in products with PAL, including gluten in 6.1% of products, cow's milk in 8.2%, hazelnut in 2.9% and peanut in 0.21%. In products without PAL- gluten was found in 3.3%, cow's milk in 2.1% and hazelnut and peanut none detected. Of those allergens that were measured in the study, all were greater than the VITAL 2.0<sup>®</sup> action levels (as below) and would indicate precautionary labelling should have been used. <sup>[11]</sup>.

Australasia has led the way with the allergen bureau's VITAL 2.0<sup>®</sup> process. Although this is one of the many risk assessment processes currently in use around the world, a major limitation of its usefulness to the consumer is that it is not possible to differentiate products which have been through this risk assessment process and remain unlabelled due to their low risk, from unlabelled products which have not been through any risk assessment process. We have identified that serious allergic reactions to undeclared allergens present in packaged foods are not rare, and presence of PAL did not appear to assist consumers in making safe food choices. Unfortunately, in the current unregulated PAL environment it is not possible to determine which foods, either labelled or unlabelled with PAL have undergone a rigorous risk assessment process. This leaves allergic individuals in an impossible situation of not being safe to eat food labelled with PAL, but not being able to determine whether foods not labelled with PAL are safe either. Our results highlight this dilemma.

We believe there currently is a need for clear, consistent, standardised and reliable PAL to be introduced. Without improved and meaningful labelling, the current state of confusion around PAL and risks of serious allergic reactions to allergic consumers will continue.

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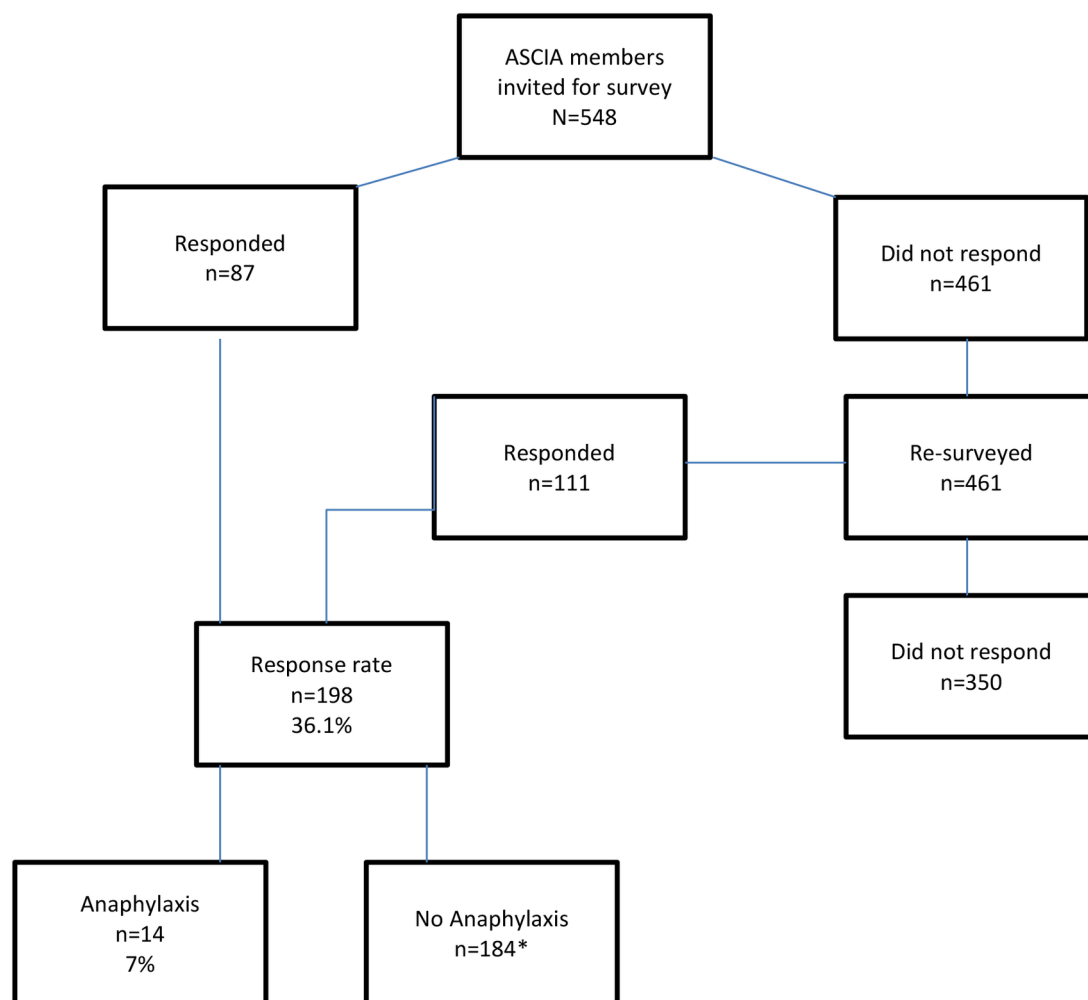
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**Table 1** Known IgE-mediated food allergies and other allergic diseases reported in the sample N=14

**Figure 1** Flow chart of responders (\* includes 12 reports of possible but unconfirmed anaphylaxis)

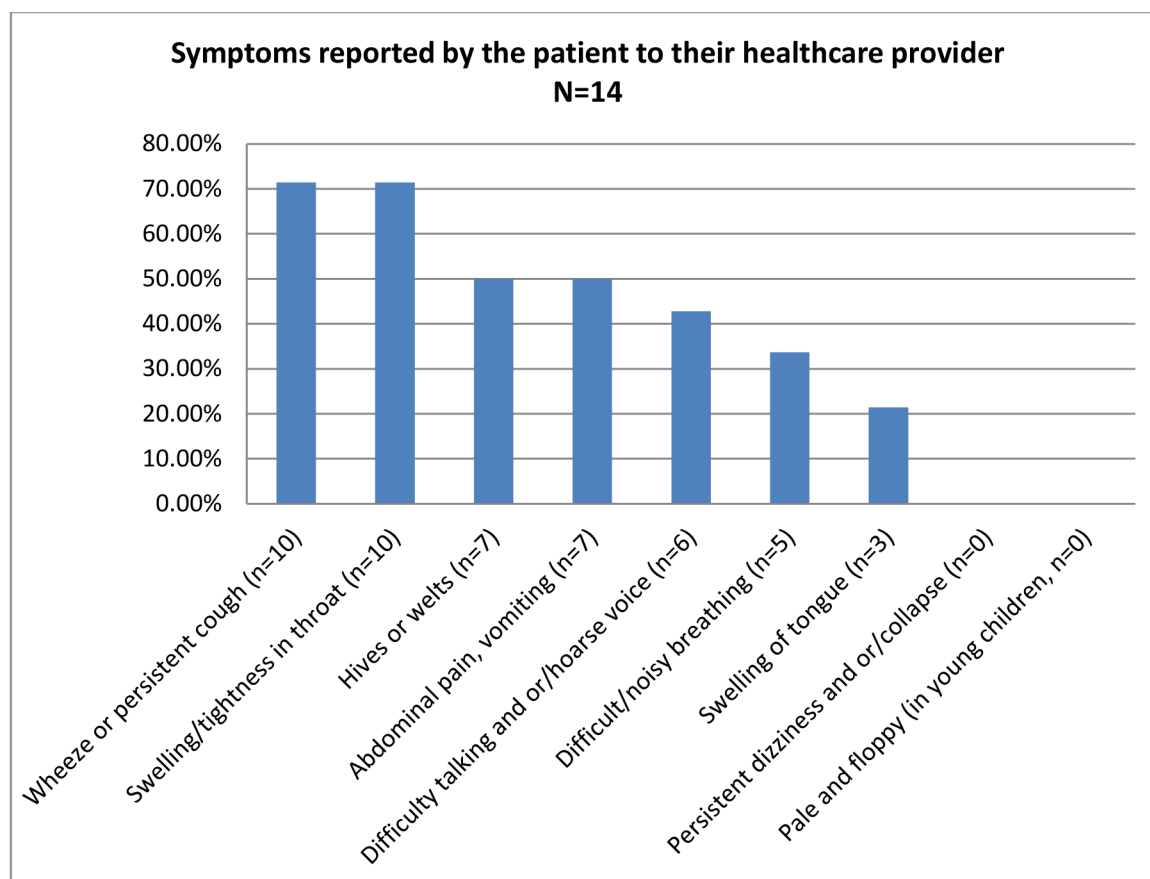
**Figure 2** Symptoms reported by the patient to the healthcare provider that took place during the episode of anaphylaxis. Every individual that has reported anaphylaxis to their healthcare provider was validated to have had anaphylaxis as per definition. The groups are not mutually exclusive.

**Figure 3** The prevalence of PAL statements on package foods that triggered anaphylaxis 12 HP answered the question about PAL labelling on the packaged product which resulted in anaphylaxis. 1 answered “don’t know “and 1 did not answer the question. Error bars represent 95% confidence intervals.



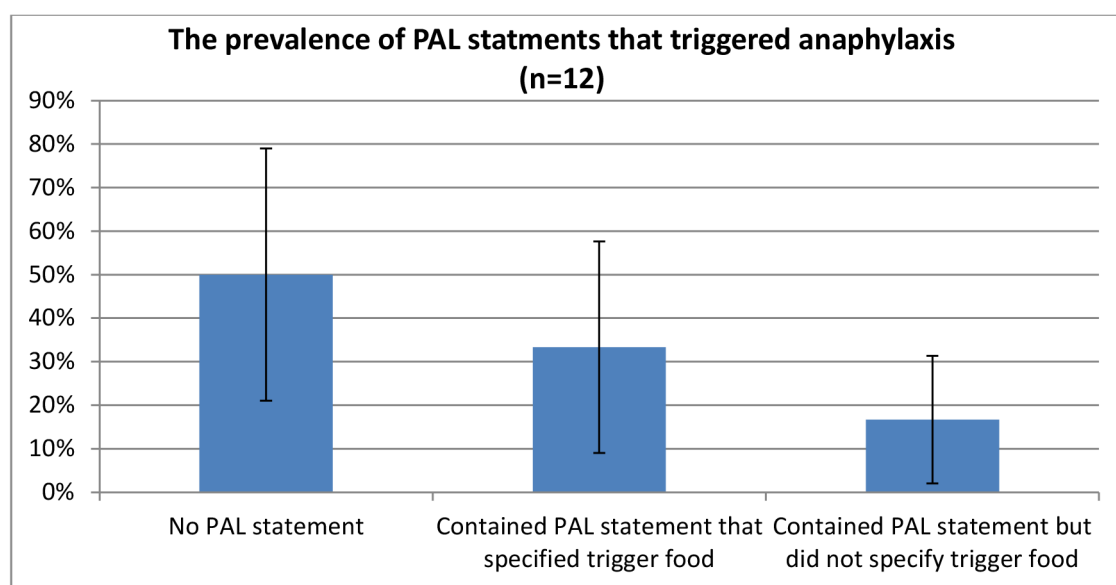
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Figure 1 (flow chart) copy.tif



**Figure 2** Symptoms reported by the patient to the healthcare provider that took place during the episode of anaphylaxis. Every individual that has reported anaphylaxis to their healthcare provider was validated to have had anaphylaxis as per definition. The groups are not mutually exclusive.

Figure 2 Symptoms reported by the patient.tif



**Figure 3** The prevalence of PAL statements on package foods that triggered anaphylaxis 12 HP answered the question about PAL labelling on the packaged product which resulted in anaphylaxis. 1 answered “don’t know “and 1 did not answer the question. Error bars represent 95% confidence intervals.

Figure 3 The prevalence of PAL.tif

**Table 1** *Known IgE-mediated food allergies and other allergic diseases reported in the sample N=14*

| Known IgE-mediated food allergies and the allergic status of subjects reported by the HCP+ |    |    |
|--------------------------------------------------------------------------------------------|----|----|
|                                                                                            | n= | %  |
| <b>IgE food allergy</b>                                                                    | 13 | 93 |
| Peanut                                                                                     | 10 | 71 |
| Milk                                                                                       | 6  | 42 |
| Egg                                                                                        | 5  | 35 |
| Cashew                                                                                     | 5  | 35 |
| Other tree nuts                                                                            | 5  | 35 |
| Walnut                                                                                     | 1  | 7  |
| Sesame                                                                                     | 1  | 7  |
| Multiple                                                                                   | 6  | 43 |
| Other allergens§                                                                           | 0  | 0  |
| Food allergy (non IgE mediated)                                                            | 0  | 0  |
| Eczema                                                                                     | 9  | 64 |
| Asthma                                                                                     | 7  | 50 |
| Allergic rhinitis                                                                          | 6  | 43 |
| Insect allergy                                                                             | 0  | 0  |
| None‡                                                                                      | 1  | 7  |

+The answers are not mutually exclusive. ‡ One patient had no history of allergic disease. §Other allergens soy, wheat, fish, prawn and other seafood.