

MANAGEMENT OF CHILDREN WITH FOOD ALLERGIES IN SOUTH AFRICA: KNOWLEDGE AND PRACTICE OF PARENTS REGARDING PRECAUTIONARY ALLERGEN LABELLING – A CROSS-SECTIONAL SURVEY

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ABSTRACT

Background: The prevalence of precautionary allergen labelling (PAL) on food products is estimated at 65%, but PAL is inconsistently applied. Consumers believe that PAL is well regulated, but their knowledge and practice of PAL is unsound, which is inconsistent with their apparent lack of trust in PAL statements. PAL should be clearly visible, easily understandable, reliable and precise in indicating 'real risk'.

Objectives: The primary objective was to determine the knowledge and practice (including adherence) of South African parents and/or caregivers regarding PAL in managing immune-mediated food allergies in children.

Methods: This study was a descriptive cross-sectional investigation with an analytical component. The study population consisted of parents and/or caregivers of children (birth to ten years) with an immune-mediated food allergy in South Africa. An online self-administered questionnaire was the instrument used for data collection.

Results: Of the 140 participants included in the study, 98% were aware that there is a special statement on food labels indicating food allergens. The majority (84%) considered the phrase 'contains' to indicate a real risk of allergen contamination, 64% for 'may contain', 56% for 'made with the same equipment' and 40% for 'made in the same factory'. Only 29% indicated that they would read the food label every time before using a food product. Non-adherence to the PAL statement 'made with the same equipment as (the allergen-containing food)' was associated with a life-threatening reaction ($p = 0.007$) or a visit to an emergency unit ($p = 0.033$).

Conclusion: This research shows that parents of children with food allergies either do not understand PAL fully or do not implement PAL statements effectively. It is vital to standardise PAL locally and globally to indicate 'real risk' or 'no risk' in order for consumers to recognise best practice in eliminating the risk of being exposed to allergen-containing food products.

Keywords: precautionary allergen labelling, knowledge, management, children, food allergies

INTRODUCTION

The prevalence of food allergies among children in developed and developing countries has increased by almost 2% since 2006, and in 2014 the estimated prevalence was 6–8%.^{1–4} The data from a recent study revealed that 2–10% of children worldwide have food allergies. The prevalence of food allergies in urban South Africa (2.5%) is similar to that of other middle-income countries.⁵ While medical diagnosis for allergies can be

extremely precise, there is no cure for food allergies. Routine clinical practice is to limit or avoid trigger foods.^{4,6–9}

Caregivers and parents are dependent on safe, accurate and understandable information about allergens on food labels in managing their children's allergies.⁸ Precautionary allergen labelling (PAL) is the term used when food may have been

exposed to an allergen during manufacturing and is labelled as such.⁸ Different phrases, for example 'may contain' or 'may contain traces', have been used by companies in allergen labelling.^{1,2,4} Although legislation on PAL was introduced in South Africa in 2012, complete transparency remains a challenging task for manufacturers.^{2,6}

Internationally, it is estimated that 65% of the food industry uses PAL statements on their products. Even though PAL is relatively well applied, its application and interpretation are inconsistent.^{2,4,6} PAL should provide a clear, precise, reliable and transparent message. The statement should indicate a 'real risk' of the food product containing the allergen.^{1,6,8,10,11} Consumers may consider PAL to be well regulated when in fact it is not. Consumers' application of their knowledge of PAL also needs to be improved. Many people believe that a lengthier statement indicates a lower risk, for example the phrase 'may contain' is considered a greater risk than the statement 'made in the same factory'.^{6,8,10} However, there is no association between the number of words used and allergen contamination.

The inconsistency and overuse of PAL has diminished its credibility and consequently consumers tend to take uncalculated risks.^{6,8,12} The products and statements become too familiar, making it difficult for consumers to determine whether a statement is true or a product is safe to consume.⁴

This study aimed to investigate the knowledge and practice of South African parents and/or caregivers regarding PAL. Understanding how South Africans interpret and understand PAL will contribute to the body of knowledge required to develop a local and global framework for standardising PAL in the future.

METHODS

This was a descriptive cross-sectional study with an analytical component. The study population comprised parents and/or caregivers of children (birth to ten years) with an immune-mediated food allergy in South Africa. Allergy clinics, allergy specialists and dietitians across South Africa were contacted and asked to participate by advertising the proposed study on their respective social media sites. In addition, the specialists and dietitians could email the questionnaire link together with a cover letter to eligible parents or, upon request, post hard copies of the questionnaires and consent forms.

The instrument for data collection was an online self-administered questionnaire developed through a web-based program, SurveyMonkey. The study was voluntary and its purpose was explained in a consent letter that preceded the questionnaire. All the data were handled confidentially and no identifiable participant data were requested. The questionnaire consisted of five sections: demographic information, severity of allergies, knowledge of PAL, the practice of PAL and practical examples. Questions were asked using multiple formats such as multiple-choice, open-ended and true/false questions.

The sample size was determined statistically with a precision of 7%, with 95% confidence for the estimates based on the binomial distribution. In order to ensure content validity, the questionnaire was sent to experts in the field for evaluation. Face validity

TABLE I: DEMOGRAPHIC CHARACTERISTICS OF THE STUDY SAMPLE

SURVEY PARTICIPANTS: PARENT AND/OR CAREGIVER (n, %)		
Relationship to the child	n	%
Mother	131	93.56
Father	6	4.29
Grandmother	2	1.43
Sister	1	0.71
Level of education	n	%
High school	21	15.00
Diploma	26	18.57
Bachelor's degree	32	22.86
Post-graduate degree	61	43.57
Province	n	%
Eastern Cape	2	1.43
Free State	1	0.71
Gauteng	60	42.86
KwaZulu-Natal	10	7.14
Limpopo	–	–
Mpumalanga	–	–
Northern Cape	–	–
North West	1	0.71
Western Cape	66	47.14
Family history of food allergies	n	%
Yes	74	52.85
No	66	47.48
Children (mean, SD)		
Age (years)	(4.02; 2.89)	
Type of allergy	n	%
Cow's milk	71	50.71
Eggs	76	54.29
Soy	32	22.86
Wheat	35	25.00
Peanuts	76	54.29
Tree nuts	60	42.86
Fish	10	7.14
Shellfish	17	12.14

* Other allergies mentioned were preservatives, colourants, banana, tomato, specific grains, citrus and mammal products

and the effectiveness of the questionnaire were established through the pilot study in November 2017. A readability test was performed on Microsoft Word and a grade level score of 8.0 was obtained. The questionnaire was not modified after the pilot study, and the results collected in the pilot study were included in the original data. The study was approved by the

TABLE II: SEVERITY OF ADVERSE EVENTS COMPARED TO ADHERENCE TO PAL STATEMENTS

	Non-adherence to PAL statements						
	Contains	May contain	May contain traces of	May be present	Made in the same factory	Made with the same equipment	Not suitable
Child had food reactions in the past year (n, %)	1, (0.94)	15, (14.15)	27, (25.47)	7, (6.60)	68, (64.15)	25, (23.58)	2, (1.89)
<i>p-value</i>	0.309	0.831	0.962	0.356	0.530	0.884	0.146
Child had a life-threatening reaction in the past year (n, %)	1, (3.45)	4, (13.79)	5, (17.24)	2, (6.90)	15, (51.72)	2, (6.90)	2, (6.90)
<i>p-value</i>	0.388	0.993	0.238	0.854	0.084	0.007*	0.217
Child visited the emergency unit in the past year due to an allergic response (n, %)	1, (2.86)	5, (14.29)	7, (20.00)	3, (8.57)	20, (57.14)	4, (11.43)	1, (2.86)
<i>p-value</i>	0.485	0.930	0.384	0.821	0.235	0.033*	0.930

Note: The participants could select more than one option for non-adherence to PAL statements.

* $p < 0.05$ = statistically significant

Health Research Ethical Committee of Stellenbosch University (S17/02/38).

STATISTICAL ANALYSIS

MS Excel was used to capture the data and the data-analysis system, STATISTICA 13 (TIBCO Software Inc., 2017) was used to analyse the data. Summary statistics were used to describe the variables. The distributions of variables were presented in histograms and/or frequency tables. A 95% confidence interval was computed for the estimation of unknown means.

The relationships between two continuous variables were analysed using regression analysis and the strength of the relationship was measured with the Pearson correlation.

The relationship between nominal variables was investigated with contingency tables and appropriate chi-square tests. A p -value of $p < 0.05$ represented statistical significance in all hypothesis testing.

RESULTS

A total of 158 participants completed the questionnaire, but the final sample size consisted of 140 participants. Of the 18 questionnaires that had to be excluded from the study, three were not included because the participants were clinicians and not caregivers. A further 15 questionnaires were excluded on the basis of the participants' indication that their child was more than ten years of age. The average completion rate for the questionnaire was 81%.

DEMOGRAPHIC INFORMATION

The demographic characteristics of survey participants are presented in Table I.

The mean age of the participants was four years (± 2.89) with minimum and maximum ages of three months and 10.75 years, respectively. The highest incidence of types of food allergy were reported for eggs and peanuts (both at 54.29%), followed by cow's milk protein (50.71%) and tree nuts (42.86%).

The participants were questioned on treatment advice, diagnoses and methods of diagnosis. The majority of the participants sought treatment advice from a medical doctor (76.43%, $n = 107$) or on social media (47.14%, $n = 6$). Approximately one-third of the participants were seeing a dietitian (29.29%, $n = 41$) and 15.71% ($n = 22$) received advice from a homeopath.

The majority of diagnoses were made by a medical doctor (92.86%, $n = 130$). Most diagnoses were made through symptoms experienced (71.43%, $n = 100$) or by means of an IgE blood test (56.42%, $n = 79$). If self-diagnosed (14.29%, $n = 20$), only half of the participants confirmed this with a medical doctor ($n = 10$).

SEVERITY OF FOOD ALLERGIES RELATED TO PAL

On average, the study participants indicated that their child had visited their healthcare professional (HCP) 1.86 times in the past 12 months. In the study sample 113 children (81.29%) had experienced a food reaction in the past year. The allergen was most likely due to exposure to cow's milk (42.85%, $n = 48$) or eggs (29.46%, $n = 33$). Symptoms most frequently experienced were hives and itching (53.57%, $n = 60$), eczema (44.64%, $n = 50$) and nasal congestion (40.17%, $n = 45$). Vomiting was experienced to a lesser degree (23.21%, $n = 26$). Thirty-one participants (22.46%) indicated that their child had experienced a life-threatening reaction in the past year due to exposure to peanuts (35.48%, $n = 11$) or eggs (22.58%, $n = 7$). Symptoms reported were consistent with anaphylaxis and included swelling of the lips, face, tongue and throat (78.12%, $n = 5$), and difficulty with breathing (75.0%, $n = 24$). Thirty-eight participants (28.35%) had visited the emergency unit in the past 12 months.

In some cases, the food reactions had resulted from parents being aware of the allergen and trying to avoid it, but failing to do so (32.09%, $n = 43$). Some parents indicated that they were unaware that the food product contained the allergen (29.85%, $n = 40$). This could have been due to inconsistent allergen

labelling. Twenty-three (17.16%) of the children were in the care of someone else during the allergic episodes and 16 children (11.94%) reacted to eating a product with a 'may contain traces' label that was not adhered to. The severity of the adverse events was compared to the adherence to PAL statements; the results are presented in Table II.

A life-threatening reaction ($p = 0.007$) or a visit to the emergency unit ($p = 0.033$) was significantly associated with non-adherence to the PAL statement 'made with the same equipment as (the allergen-containing food)'.

More children had a food reaction, or a life-threatening reaction, or visited the emergency care unit in the past year when the PAL statement 'made in the same factory' was ignored.

KNOWLEDGE OF PAL

The vast majority of the participants (98%, $n = 128$) were aware that there is a special statement indicating food allergies on food labels and only 56% ($n = 74$) indicated that their HCP had discussed allergen labelling with them.

The participants were asked about their understanding of certain PAL statements. Figure 1 indicates the percentage of statements that are perceived as being 'true'. From the findings (presented in Figure 1), it is clear that participants' thoughts are conflicted.

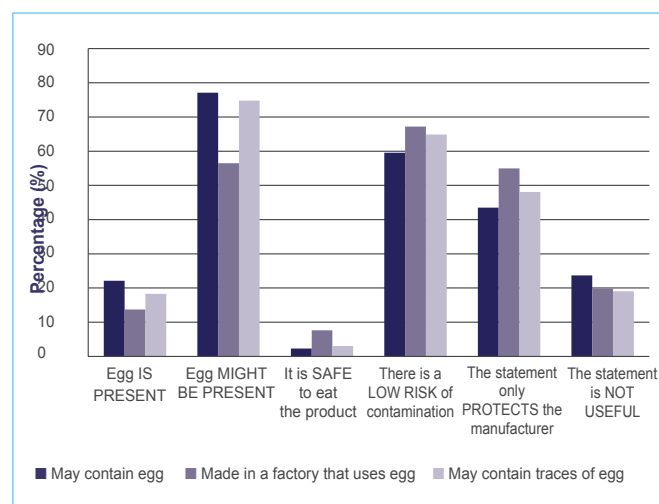


Figure 1: Knowledge of PAL

Although they see clearly that egg might be present and that the product is not safe to consume, they also say that there is a low risk of contamination and that the statement only protects the manufacturer.

Figure 2 indicates the perceived difference in risk associated with PAL statements. The percentage indicates the perceived 'real risk' of allergen contamination.

The participants ranked the PAL statements that indicated a 'real risk' from highest to lowest. The perception of 'real risk' was asked in two different questions in the questionnaire and the findings of the two questions was the same. The statement 'made with the same equipment' received the second lowest risk

score and 'made in a factory' that uses the allergen received the lowest real risk score, yet when ignored it had the most episodes recorded (as seen in Table II).

PRACTICE OF PAL

The results regarding PAL practice, although interesting, were concerning in that 88.46% ($n = 115$) and 92.31% ($n = 120$) of the participants would read ingredient and allergen information, respectively; however, none of the participants specified that they read the labels during food preparation. It is concerning that the lowest number of participants (29.23%, $n = 38$) would read the food label every time before they used a food product. Furthermore, only one-third of the participants indicated that they read the label when buying the product for the first time (30.77%, $n = 40$), and only 38.46% ($n = 50$) would read food labels most of the time when purchasing food. All the participants, however, indicated that they would teach or had taught their child how to read food-allergy labels themselves.

Eighty-five participants (65.38%) indicated that they would give their child a food product with a label 'made in a factory that uses (name of allergen)' and 25.38% ($n = 33$) that they would give a food product labelled 'may contain traces of'. In purchasing and consumption practice, 23.85% ($n = 31$) would trust a food product labelled 'made with the same equipment'. These three statements were also considered a 'lower risk' of allergen contamination according to Figure 2. Only 1.53% ($n = 2$) and 3.06% ($n = 4$) of parents would give their child a food product labelled as 'contains' or 'not suitable for allergen sufferers'.

The participants were asked to look at the labels of Product A and Product B and select which product they would give to a child with a cow's milk, soy or peanut allergy, respectively (see Table III).

TABLE III: PARENTS' PRACTICAL INTERPRETATION OF FOOD LABELS

PRODUCT A	PRODUCT B
Ingredients: whole-wheat flour (gluten), vegetable oil (palm oil), butter (milk), golden syrup, preservative, whey powder (milk), raising agent, yeast (soy), emulsifier Allergens: wheat (gluten), cow's milk, soy Made in a factory that uses peanuts and tree nuts	Ingredients: wheat flour (gluten), vegetable oil (palm kernel, palm fruit), sugar, invert syrup, emulsifier, golden syrup Contains: wheat (gluten), barley (gluten) May contain: soy

Whereas 114 participants completed the three practical example questions, only 42% answered all three questions correctly. There is a clear need for more education about allergen food labels and PAL statements.

REASONS WHY PARENTS AND/OR CAREGIVERS DO NOT ADHERE TO PAL

The following reasons were given why the participants did not adhere to PAL (see Figure 3). Only 15.04% ($n = 17$) of the participants indicated that they would not give their child any food product with a PAL statement. A quarter of the participants

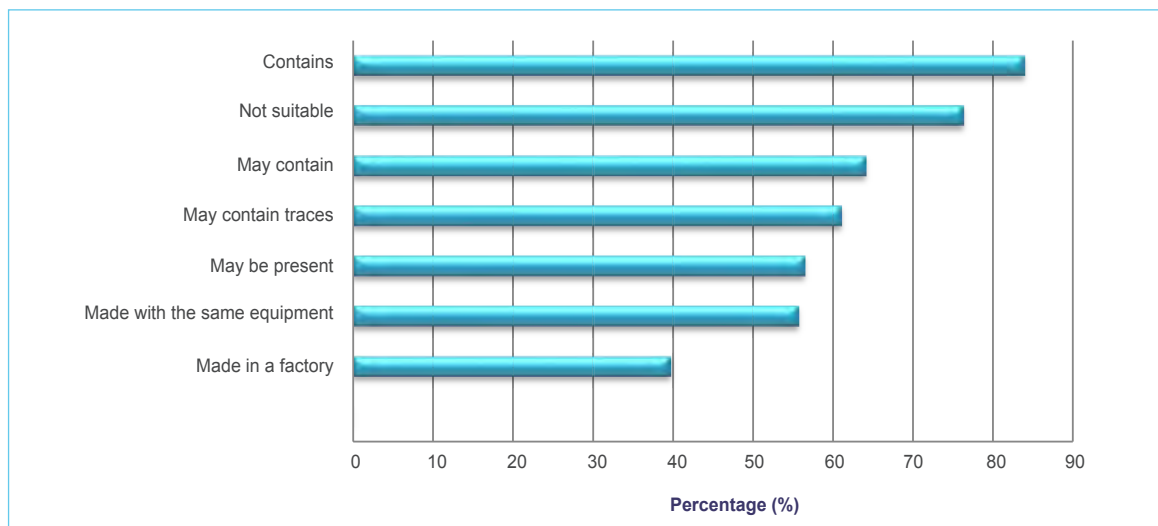


Figure 2: Perceptions of real risk

indicated that the statements were purely there to protect the manufacturer (25.66%, $n = 29$).

When asking the participants for recommendations, most (83.62%, $n = 97$) indicated that they would find more specific information on allergy labelling useful and some (97.41%, $n = 113$) believed that labelling should be included in pre-packaged foods.

DISCUSSION

This is the first South African study aimed at determining the knowledge and practice of parents with food-allergic children regarding PAL. From the results, some clear trends have been identified. These are discussed in the next section.

PAL STATEMENT: 'MADE WITH THE SAME EQUIPMENT AS (THE ALLERGEN-CONTAINING FOOD)'

A life-threatening reaction or a visit to the emergency unit was significantly associated with non-adherence to the PAL statement 'made with the same equipment as (the allergen-containing food)'. But this statement was ranked second to last in the perception of 'real risk', indicating that it may often be ignored in practice. This supports the evidence that consumers believe that PAL phrases indicate and reflect a hierarchical system, which in fact is poorly and inadequately regulated. It has been found that lengthier phrases are also considered a lower risk; therefore, the statement 'made with the same equipment' is considered a low risk.^{1,7,10} In the current study, this statement had contributed to the adverse events, bearing in mind different levels of severity of allergy. Ultimately, we are faced with the question: How can we indicate and communicate a 'real risk' of food allergies on a product label?

A similar study among HCPs in Australia found that the statement 'made with the same equipment' was viewed as the highest 'real risk' of allergen contamination.¹³ However, 30–40% of Australian parents in the study stated that they would ignore this label, whereas only 30% would ignore the label 'may contain'.¹³ It seems that practices among Australian parents are similar to

those among South African parents in that they too consider a shorter PAL phrase as indicating a higher or the highest 'real risk'. HCPs, on the other hand, view the same statements differently. Therefore, clear and concise education is of extreme importance, but its success depends on a universal, regulated labelling framework being introduced that indicates 'real risk'.

KNOWLEDGE AND PRACTICE OF PAL

The key to managing food allergies is education and the strict avoidance of culprit foods.^{1,4,6–9} In the current study, 44% of parents had not received adequate information from their HCP. In the Australian study, 40% of HCPs regarded PAL as unimportant.¹³ This is a matter of concern because at least 40% of HCPs do not inform parents about the importance of PAL and at least 40% of parents are misinformed regarding PAL. It has been shown, though, that food-allergy education improves parents' management skills.⁷ Parents are acutely aware that they need to avoid allergenic foods, but applying that awareness of the risks remains challenging. Some children still have an adverse event despite parents trying to avoid the allergen. Could it be that parents do not understand PAL? Or is PAL not a true indication of risk?

The participants' understanding of PAL was inconsistent and few could confirm with confidence whether the allergen was present in the product. Most stated that the allergen 'might be present' and did not consider the product safe to consume, yet the risk of contamination was regarded as low. Many believed that the statement served mainly to protect the manufacturer. This indicates clear confusion in understanding PAL. The study also indicates that PAL is ignored more often if there has been no adverse reaction after consumption; this would influence the trust consumers have in PAL statements.

When we compare their knowledge and understanding of PAL statements, consumers in this study tended to think that the statement 'made in a factory that uses (name of allergen)' would protect the manufacturer to a greater extent than the 'may contain' or 'may contain traces of' statements (see Figure 1).

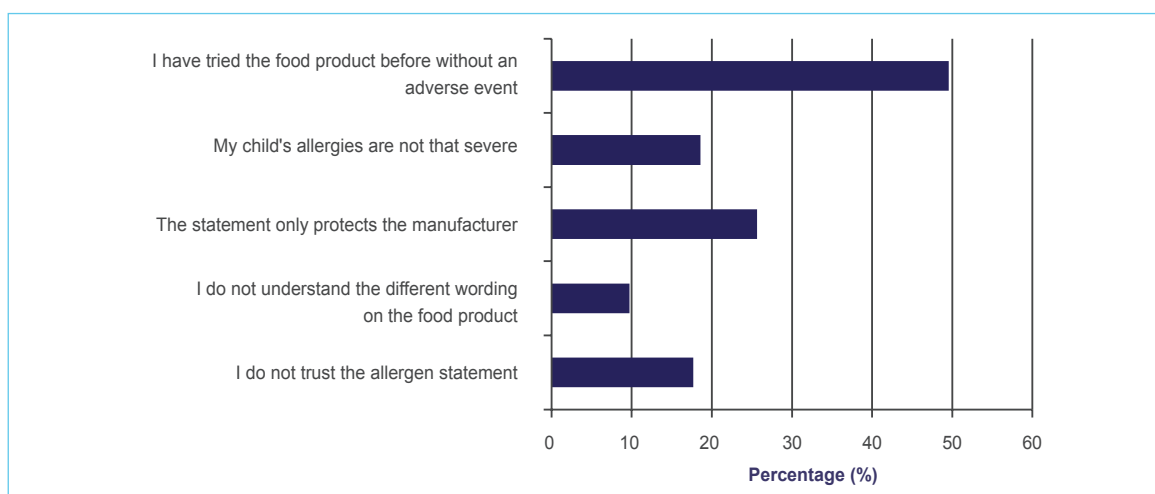


Figure 3: Reasons for non-adherence to PAL

Most participants (84%) considered the phrase 'contains (name of allergen)' to indicate a real risk of allergen contamination, 64% for 'may contain', 61% for 'may contain traces', 56% for 'made with the same equipment' and 40% for 'made in a factory that uses (name of allergen)'.

The data from this study are similar to those derived from an investigation conducted by Zurzolo et al (2013) regarding the reading of food allergen labels.¹⁴ In both studies, 30% of parents would read the labels only the first time they bought a food product and 30% would read the labels every time. None of the participants in that study stated that they read allergen information during food preparation.

This practice is especially concerning to parents whose children eat outside of the home because parents do not trust the school system to manage food allergies effectively.⁷ If the school cook – who does not necessarily purchase the food – does not read the labels during food preparation, many PAL warnings could be overlooked altogether. Similarly, if one parent buys the food product and another parent cooks it, and if the food product and labels are not read on both occasions, it could lead to a possible adverse event due to PAL statements being ignored.

In the current study, 42% of parents answered all three practice questions regarding the reading of PAL statements correctly, yet 81% of children had experienced a food reaction in the past year. This could indicate that knowledge is not always put into practice and supports the data that decisions are made based on a self-determined risk assessment.^{1,8}

REASONS FOR POOR ADHERENCE TO PAL

This study revealed that the two primary reasons for not adhering to PAL are that parents became complacent if their child had not previously had an adverse reaction to the food product and that they believed that PAL statements only protected the manufacturer. This supports data that PAL has increasingly less credibility and that consumers take an uncalculated risk when the food product has been tolerated before.^{6,8}

While the term 'traces' is often considered ineffective in PAL

labelling, only 25% of participants in this study confirmed that they would ignore the statement 'may contain traces of'.^{6,8,12}

The key strength of the study was the 81% completion rate of the questionnaire. Although possible bias in parents' self-reporting may have presented a limitation, this approach was appropriate in determining knowledge and practice.

Some limitations of the study are that due to the inclusion criteria (parents with at least a high school education and with children aged 0–10 years), this study is not representative of the general South African population. The sample size was calculated as 200 participants, but only 158 participants completed the study, compromising the precision of the study. Very little literature on knowledge and practice of PAL is available; however, this study did some groundwork for future research. Moreover, the questionnaire was self-developed; it could have been more effective to use a standardised tool already used in other studies.

CONCLUSION

It is clear that the parents of children with food allergies do not fully know how to understand and implement PAL and that these statements are conflicting and confusing. PAL statements are often ignored, which may contribute to adverse events. Therefore, if trust in the PAL statements is inadequate, how can proper adherence be expected?

Bearing in mind that food allergies are experienced to different degrees of severity, the data may appear to be contradictory. However, they all point to one thought: the need to standardise PAL globally to indicate 'real risk' or 'no risk' in order for consumers to know and understand the best practice for eliminating the risk of being exposed to allergen-containing food products.

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DECLARATION OF CONFLICT OF INTEREST

The authors declare no conflict of interest.

This article has been peer reviewed.

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