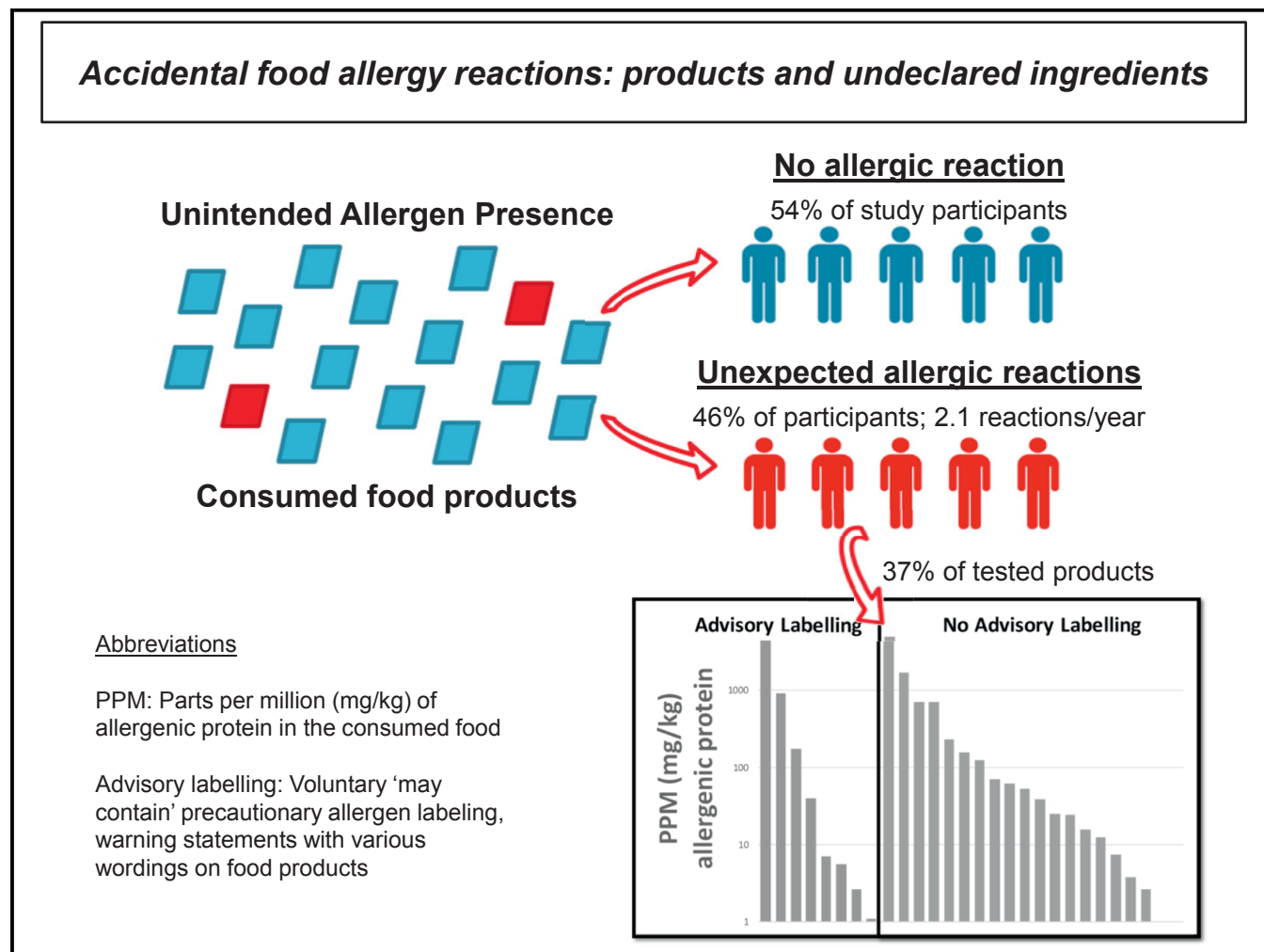


Accidental food allergy reactions: Products and undeclared ingredients

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GRAPHICAL ABSTRACT



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Background: Accidental allergic reactions to food are frequent and can be severe and even fatal.

Objective: We sought to analyze the culprit food products and levels of unexpected allergens in accidental reactions.

Methods: A prospective cohort study was conducted in adults (n = 157) with a physician-confirmed diagnosis of food allergy. During a 1-year follow-up, 73 patients reported accidental allergic reactions and the culprit food products. Food samples received (n = 51) were analyzed for a wide range of suspected noningredient allergens, and risk was quantified.

Results: A very diverse range of food products was responsible for the unexpected allergic reactions. Thirty-seven percent (19/51) of products analyzed had 1 to 4 culprit allergens identified that were not supposed to be present according to the ingredient declaration. Concentrations varied from 1 to 5000 mg of protein of the allergenic food per kilogram of food product and were greatest for peanut, milk, and sesame. Milk proteins posed the highest estimated risk for objective allergic reactions. The intake of culprit allergens by patients varied considerably. For those cases in which culprit allergens were detected, the intake of at least 1 allergen exceeded the reference dose or a culprit allergen with a yet unknown reference dose was present. Both patient neglect of precautionary allergen labeling statements and omission of using a precautionary allergen labeling statement by food manufacturers seem to contribute to accidental reactions.

Conclusion: A wide range of food products are causing accidental reactions in patients with food allergy. Eight different allergens not declared on the ingredient lists were detected in the culprit food products, all of which were representative of allergens regulated in the European Union. (*J Allergy Clin Immunol* 2018;■■■:■■■-■■■.)

Key words: Accidental allergic reaction, allergen management, allergen labeling, allergen intake, food allergy, food product, precautionary allergen labeling, reference dose, undeclared allergen

Food allergy is a serious health problem affecting 1% to 3% of the population.¹ For many patients with food allergy, these allergies are best managed by individualized avoidance of the allergenic food.

Legislation on food labeling is implemented in most regions of the world to help patients with a food allergy. In Europe the presence of 14 ingredients that can cause allergy or intolerance must be listed on food labels of prepackaged foods and be available for unpacked foods according to European Union (EU) Regulation 1169/2011.² However, allergens can accidentally end up in food as a result of contamination during transport, storage, or processing of food. For this, “may contain” precautionary allergen labeling (PAL) is often used in cases in which the absence of allergens cannot be guaranteed. Allergen management guidance lacks thresholds for applying a precautionary allergen statement. This has led to widespread use of PAL on prepackaged foods, even when the chance and expected level of contamination is very low. At the same time, several studies have shown that products without PAL contained undeclared allergens at detectable levels,^{3,4} presenting a potential health risk for the allergic population.⁵⁻⁸ In addition, precautionary statements vary widely in wording, adding to confusion for allergic patients about their meaning.⁸ Consequently, PAL has lost its credibility,

Abbreviations used

EU: European Union
LOD: Limit of detection
PAL: Precautionary allergen labeling

and allergic patients increasingly ignore the precautionary allergen statement.^{9,10}

In the present situation accidental allergic reactions to food occur frequently among allergic patients, including severe and fatal reactions.¹¹⁻¹⁵ The comparability between studies is limited because of different time frames and study populations.¹¹ In those studies, eating outside the home and prepackaged foods are both mentioned frequently as main causes together with patient factors, such as ignoring or missing the (precautionary allergen) label or not informing restaurant staff. However, a systematic study on the relationship between allergic reactions, foods, and the possible unintentional presence of allergens, such as noningredient allergens, is lacking.

Recently, we followed a well-defined adult patient cohort with food allergy (n = 157) for 1 year to study the frequency, severity, and causes of accidental reactions. The frequency was approximately 1 per person per year. Almost half of the patients reported unexpected reactions. Of those who reacted, food reactions occurred on average 2 times per year (range, 1-11).¹⁶ Here we focus on investigating the type of food products and allergenic protein sources causing these unexpected allergic reactions in the daily lives of this patient group. Products for which the unintended (ie, noningredient) presence of culprit allergens was suspected were analyzed for these allergens. The dose estimated to cause the allergic reaction in individual patients and the potential risk for the allergic population were analyzed.

METHODS

Study design and population

A longitudinal prospective cohort study was conducted by the University Medical Centre Utrecht and TNO, The Netherlands, to collect data on frequency, causes (both product and patient related), severity, and consequences of accidental allergic reactions. Recruitment of participants started in January 2012 and ended in July 2014.

Adult patients (age range, 18-70 years; mean age, 35.3 years; SD, 12.7 years) with a physician-confirmed diagnosed food allergy reported their accidental reactions through a secured Internet portal over 1 year. The physician-diagnosed food allergy was based on the patient's convincing history of allergic complaints to food and a positive skin prick test response and/or IgE level and/or positive food challenge test response. Dietary advice was given per food allergy. This advice was to avoid the allergen present as an ingredient in all cases, and advice for allergens on PAL statements was individualized. Patients who did not have a computer or Internet access and patients without the ability to read or write the Dutch language were excluded.

The outcome for the total study population on frequency, causes, severity, and consequences for the patient, such as medical intervention and sick leave, are described separately.¹⁶ The focus in the present article is on the food products that were assigned to the accidental allergic reactions by the patients and the allergenic protein sources involved.

All patients signed an informed consent form before inclusion. According to the local Medical Ethical Committee, the Medical Research Involving Human Subjects Act did not apply to the study, and therefore official approval by the Medical Ethical Research Committee was not necessary (protocol no. 11-309/c).

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