

Review article

A framework for measuring the social impact of food allergy across Europe: a EuroPrevall state of the art paper

This state of the art paper has been developed through EuroPrevall, a European multicentre research project funded by the European Union which aims to improve quality of life for food allergic individuals. Food allergy (whether clinically diagnosed or self-perceived) represents a major health issue in Western societies and may have a considerably greater impact on society than was previously believed. However, the social impact of food allergy has never been systematically investigated using validated instruments. Combining the information from studies on health-related quality of life (HRQoL) with epidemiological data on prevalence will ultimately give some indication of the magnitude of the social impact of food allergy in Europe. HRQoL can be assessed with disease-specific questionnaires, which are being developed in EuroPrevall. These instruments will be used to identify HRQoL problems associated with food allergy, and to assess the effectiveness of interventions and to guide the development of regulatory policies.

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Key words: EuroPrevall; food allergy; gender; health-related quality of life; social impact.

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Accepted for publication 23 November 2006

Adverse reactions to foods, including IgE-mediated food allergies, represent a major health-issue in Western societies. It has been estimated that in the general population approximately 4–6% of children and 1–3% of adults experience food allergy (1). There is some evidence to suggest that the prevalence has increased over the last 10 years (2). This is demonstrated by the increase in emergency room visits due to food allergy in the UK, which have increased by a factor of six over a decade, accompanied by an increase in the incidence of anaphylaxis caused by food allergy (3). Another remarkable observation is that the prevalence of perceived food allergy seems to be much higher than verified food allergy, up to 22% of the adult population (4). This may

be related to inadequate diagnosis of food allergy, in part reflecting the lack of adequate provision of relevant health services.

Adverse reactions to foods (including IgE-mediated allergies), clinically or self-diagnosed, may have a considerably greater impact on society than has previously been believed. The social functioning of individuals with a food allergy, or activities in families with an allergic child or family member, may be seriously disrupted by the need for continuous vigilance to avoid foods to which they are (or believe to be) allergic (5). In cases of individuals with self-diagnosed food allergy, the majority may be restricting their diet unnecessarily and consequently running the risk of nutritionally compromising themselves or

becoming deficient in specific nutrients (6, 7). Furthermore, such dietary management disrupts social or family life, and could be costly to implement both in time and money (8). However, the effects of food allergy are not only limited to individuals or households. The food industry may also experience an extra burden of costs due to food allergy (9). This may, for example, result from legislative changes aimed at improving consumer protection such as the new European Union (EU)-legislation on food labelling that came into force in November 2005 (EU Directive 2003/89/EC amending Directive 2000/13/EC). The onus of responsibility falls to the food manufacturer, who is required to manage production processes to ensure allergenic ingredients are labelled. At the present time, the potential social impact and economic costs of food allergy on the individual, families, health-related services and food industry are not well understood.

EuroPrevall is a European multidisciplinary and multi-centre research project funded by the EU. Its mandate is to investigate the prevalence, cost, and basis of food allergy, and to improve quality of life for food allergic people (10). To assess the socio-economic impact of food allergy, and provide benchmarks to assess the effectiveness of interventions developed to manage the disease, validated instruments are needed. One of the major objectives of EuroPrevall is to develop and validate instruments to determine the impact of food allergy on the health-related quality of life (HRQoL) of allergy sufferers and their families, and to assess the economic costs. A framework for measuring costs of food allergy to society has already been published (11). However, there is an urgent need to initiate a similar enquiry into the social impact of food allergy. We will provide an overview of current knowledge and limitations in this area, and describe the research strategies being developed in the EuroPrevall project to obtain this missing information. Finally, the importance of assessing the social impact of food allergy and the practical implications will be discussed.

Social impact of food allergy

The social impact of food allergy can be assessed using measurements of HRQoL in food allergic individuals. Quality of life is a broad concept that pertains to an individual's overall satisfaction with his or her life. It has been defined by the World Health Organisation (WHO) as 'the individual's perception of their position of life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns' (12). The component of overall quality of life that pertains to an individual's health is called health-related quality of life and is defined as the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient (13). It contains three domains: the social, the psychological and the physical

state. It is important to understand that a similar level of objective clinical impairment may have a different impact on HRQoL in different patients because individuals vary in their tolerance levels and subjective perceptions of ill-health (14). In addition, HRQoL measures the impairments that patients themselves consider to be important, rather than focusing on what is considered important by external observers, such as doctors or nurses (15).

The HRQoL is measured using specially designed and tested instruments, which measure people's ability to function in their everyday lives. There are two major types used in clinical trials and practice: 'generic' and 'disease-specific' instruments. Generic instruments can be used to evaluate and compare different disease states. Disease-specific instruments do not allow comparison between different diseases, but are more responsive than generic instruments and therefore more likely to detect small but clinically important changes in patients' impairments resulting from a specific disease or disorder (16).

There are only a few studies that have investigated the impact of food allergy on HRQoL. By using generic questionnaires (Impact on Family Scale) it has been shown that daily life is significantly more disrupted in peanut allergic individuals than in individuals with a rheumatic disease (17). Moreover, general health perception, emotional impact on the parent and limitation of family activities of parents with food-allergic children were found to be impaired compared with established norms, using the Children's Health Questionnaire (18). In addition, it has also been reported, using the Medical Outcome Trust Short Form 36 Health Survey (SF-36), that females with food allergy showed significantly more bodily pain and impairment of general health and social functioning in comparison with females with other allergy-like conditions (19). Recently, two studies were published on the development of preliminary questionnaires to assess the parental adjustment to and coping with children's food allergy (20) and to determine the impact of food allergy on the daily activities of food allergic (FA) children and their families (21). Both questionnaires are administered to the parents. The last study reported that food allergy had a significant impact on almost all aspects of daily life.

Currently, there is only one validated HRQoL questionnaire specific for food allergy available: the Food Allergy Quality of Life – Parental Burden (FAQL-PB) questionnaire (22). It is administered to the parents and measures the parental burden associated with having a child with food allergy. Internal validity, reliability and cross-sectional validity were established, but the instrument was not longitudinally validated. This questionnaire represents a milestone in the field of food allergy and quality of life. However it has some significant limitations. First, the questionnaire was developed for allergic children and is, therefore, not suitable for allergic adults. Secondly, the questionnaire measures the parental quality of life, not the quality of life of the child, and thirdly no

distinction was made between different age groups of children in the development of the questionnaire. Moreover, the questionnaire is time bound, inquiring only about allergic incidents during the week preceding administration.

Assessing HRQoL in EuroPrevall

To complement the existing instruments, and to develop instruments that can assess broader questions related to the quality of life of food allergic patients, new HRQoL questionnaires will be developed and validated within the EuroPrevall project in the Netherlands and Ireland. These questionnaires will cover all ages in childhood and adulthood. Questionnaires for the youngest children will be parent-administered and questionnaires for the older children, adolescents and adults will be self-administered. In addition, the reporting period will be less restricted. The development of these questionnaires will start with 'item generation' in which all possible problems associated with food allergy are generated, followed by 'item reduction' in which the most important items are selected. These prototype questionnaires will be cross-sectionally validated followed by longitudinal validation. The final questionnaires will be translated into the languages used in different European countries enabling cross-cultural comparison of the questionnaires. A more-detailed description of the development of these questionnaires can be found elsewhere (23).

In EuroPrevall it will be of interest to compare the outcomes of the questionnaires completed by the parents to the outcomes of the questionnaires completed by the children themselves to investigate the agreement or disagreement between them. In addition, special emphasis will be put on the gender dimension, because there may be considerable differences between men and women in how they experience and cope with their food allergy (24). To date, one study has assessed gender differences in the quality of life of the family members of children with peanut allergy. The results showed that mothers experienced significantly poorer psychological quality of life, greater anxiety and stress than fathers or sibling(s). In addition, mothers rated their child's quality of life significantly worse compared with the peanut allergic child's own ratings or the proxy ratings of the sibling and father (25).

In addition to the development of questionnaires to measure HRQoL, research will be conducted to assess how the quality of life of food allergic consumers can be improved. One of the research topics will focus on how to optimize information provision through effective allergen labelling. The existing literature indicates that food allergic consumers experience stress and potentially impaired quality of life as a result of poor labelling practices and lack of information about their food allergy (26). Despite the new EU labelling legislation, allergic

consumers are still not completely sure about the safety of products. This uncertainty could be caused by fear of cross-contamination, unlabelled products (for example those which are not packaged), changes in ingredients and the difficulty of understanding product labels (27–31). It has been suggested that improved product ingredient labelling will reduce allergic reactions and simplify allergy management. However, it may also increase choice restriction when allergen-derived ingredients are indicated on the label that are tolerated by allergic individuals (32). In addition to the EU labelling legislation, companies use precautionary labelling to alert consumers on the chance of contamination during the production process, which may increase the choice restriction of food allergic consumers even more (33).

To improve labelling practices, consumer preferences for different food labelling strategies will be investigated, as well as the benefits of new Information and Communication Technology (ICT) approaches to delivering targeted information. Consumer preferences for the implementation of such new approaches, together with feasibility of adoption, will be assessed. This will provide the basis for a tested and implementable set of guidelines underpinning the development of new approaches to deliver necessary information to the allergic consumer, which is essential if food allergic consumers are to lead a life which is as normal as possible (34). Such information interventions may have a positive effect on the quality of life of food allergic consumers, which can be assessed using 'before and after' evaluations of the HRQoL instruments.

Relevance and practical implementation

Magnitude of social impact of food allergy across Europe

One of the major aims of the EuroPrevall project is to assess the social impact of food allergies, and their potential mitigation, to the European Community. To realize this, it is important to combine the information from studies on HRQoL with epidemiological data on prevalence. This will ultimately give some indication of the magnitude of the social impact of food allergy in Europe. The impact of food allergy on HRQoL may differ according to the type of food to which a particular individual is allergic, the severity of allergy symptoms and the number of foods to which one is allergic (single or multiple). Furthermore, the impact may also be dependent on threshold (the amount of an allergic food that is needed to trigger an allergic reaction), or the age and gender of the allergic individual in question. This information is essential if healthcare planning and food safety assessments are to be deployed with best effect to support the allergic consumer in managing their condition.

In a European context, it is important to determine whether cross-cultural differences in the social impact of

food allergy can be identified. A case in point, it has been shown that the prevalence of 'perceived' food allergy differs significantly across multiple countries, ranging from 4.6% in Spain to 19.1% in Australia (35). This is probably due to differences in the prevalence of real food allergy, but may also be due to cultural differences. In addition the impact of food allergy on quality of life may differ due to cultural differences. It is important to take this into account when measuring HRQoL in different countries.

Determinate problems, effectiveness of interventions and prioritizing

The effect of legislation regarding food allergy on the social impact of food allergies, on both allergy sufferers and the wider community, has never been assessed. For example, it is not understood to what extent the new labelling legislation improves the quality of life of allergy sufferers. Nor has an assessment been made of how resulting benefits to consumers can be balanced against the costs to the food industry when implementing much more stringent hazard control procedures in food manufacturing. Such costs are ultimately passed on to the consumer. To assess the impact of (regulatory) interventions, it is important to first quantify the impact of food allergy on HRQoL.

By using HRQoL questionnaires, it may for example be ascertained that the quality of life of food allergic patients is negatively affected by the need for continuous vigilance when eating outside the home. In this case, regulations need to be developed that enforce the need for effective training in the catering sector. If some food allergies have a greater impact on quality of life, these should be prioritized in terms of regulatory interventions and legislative measures. Other applications of HRQoL

measures include the identification of the effectiveness of interventions in clinical trials. For example, if proper diagnosis, expert dietary interventions, counselling regarding accidental exposure management, or a future treatment is found to have a positive effect on HRQoL, then resources can be directed towards these interventions.

Conclusions

A necessary first step to assess the social impact of food allergy is the development of new HRQoL instruments. When these instruments are available, HRQoL problems associated with food allergy can be identified and this may be followed by the development of improved approaches to manage these problems. The instruments may also be used to assess the usefulness of new legislation and guidelines regarding allergen management in food manufacturing and catering industries. Finally, HRQoL measurement may also facilitate the more efficient allocation of resources within health services, for example to support more effective clinical diagnostic methods, if these can be demonstrated to have a significant positive impact. Continuous application of such instruments and analysis of changes with time may identify emerging social problems associated with food allergy, and identify differences across European populations.

Acknowledgments

This work was funded by the EU through the EuroPrevall project (FOOD-CT-2005-514000). CM was also supported by the BBSRC Competitive strategic grant.

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