Social and Economic Costs of Food Allergies in Europe: Development of a Questionnaire to Measure Costs and Health Utility

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Objectives. To develop a questionnaire to measure the additional social costs of food allergies (FAs).

Data Source and Study Setting. People with FAs and sampled members of the general population (with and without FAs) in the Netherlands and the United Kingdom in 2006.

Study Design. (1) Literature review. (2) Focus group to identify key costs of FAs and seek views on the questionnaires. (3) Pilot survey to test the questionnaires in cases and controls.

Data Collection. Twenty-eight participants in the United Kingdom and the Netherlands with clinically or self-diagnosed FAs took part in one of five focus groups. A case-control postal survey was conducted in the United Kingdom and the Netherlands (with 125 FA cases and 62 controls).

Principal Findings. Methods exist to measure social costs in chronic illness, but not FAs. Focus groups found features of FAs likely to impact costs of living. Pilot results suggest higher costs of living and health care costs, and well-being in FAs.

Conclusion. The questionnaire is proposed for use in wider European and other comparative studies of FAs.

Key Words. Health economics, survey and research design, health care costs, chronic disease, EuroPrevall, food allergies

Very little is known about the socioeconomic consequences of food allergies (FAs). These may stretch beyond the individuals with FAs to other family members, households, and to other sectors in society. Policy makers require information about the socioeconomic consequences of FAs in order to develop appropriate and cost-effective regulatory frameworks regarding consumer protection and to make decisions concerning the provision of health care

services. In addition, this information is of relevance to the food industry, which may need to implement effective traceability and labeling strategies regarding allergenic food and ingredients in line with national and international regulation.

The incidence and prevalence of FAs in developed and developing countries is uncertain. A meta-analysis found that between 2 and 35 percent of populations in Europe believe they have FAs (Rona et al. 2007); the lower figures were found in studies where diagnostic tests for IgE-mediated allergies were applied, and higher figures were found where self-perceived FAs were reported. In the United States, Vierk et al. (2007) found that 5.3 percent of adults reported a doctor-diagnosed FA and just under 10 percent reported self-perceived FA. Whatever the prevalence of FAs, there is very little information about the socioeconomic impacts associated with them (Miles et al. 2005; De Blok et al. 2007).

This paper describes the development of questionnaires to measure the costs of FAs in Europe (which could also be adapted for use in the United States). The research was carried out within the framework developed by Miles et al. (2005). Following a systematic review of articles published in peer-reviewed journals before February 2004, Miles et al. (2005) recommended that the costs of FAs should include the direct, indirect, and intangible costs of FAs to all stakeholders: the individual, households, the public sector (particularly the health sector), and industry. Working within this framework, the direct costs for individuals and households are estimated by including the costs of special foods and equipment, services to help with domestic duties and childcare, and the costs of traveling to and paying for medical treatments or health service for individuals and households, costs of seeking information about FAs; direct cost to the public sector are estimated in terms of health care provision. Indirect costs for individuals are measured in terms of lost opportunity, including time lost in seeking health care and health information, in

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paid and unpaid work, in voluntary work and leisure activities, and in terms of reduced quality of life.

AIMS AND OBJECTIVES

The main objective of the research was to develop a questionnaire to collect costs of FAs at the level of individuals and households, including the use of health service and related resources and to understand the potential for increasing health utility through treatments for people with FAs. A secondary objective was to assess the viability of using case-control surveys to analyze the costs of FAs.

The aims were as follows:

- Search for and review existing instruments and scales to measure costs of FA.
- Test available generic instruments and scales using qualitative research.
- Test and validate the developed instrument in a pilot case-control survey.

As it was a pilot survey, the study did not aim to obtain representative samples of either food allergic or nonfood allergic populations. We did not aim to carry out this survey with people who had confirmed/diagnosed FAs. Self-perceived FA is likely to include various types of food sensitivity/intolerance, which are clinically different from FA. For the purposes of this research we wanted to recruit people who believed they had a FA, to assess if they behaved differently from those who believed they did not have a FA. This builds on methods carried out in parallel studies of consumer preferences for food labeling (see Cornelisse-Vermaat et al. 2008).

METHODS

Reviews of Scales and Instruments

A range of U.K., the Netherlands, and other official household questionnaires were reviewed to find validated questions to estimate household expenditure and cost of leisure activities (Expenditure and Food Survey, ONS 2005), income scales (WERS 2004), household labor (Zwart et al. 2002), health status and disabilities (WHO), and health care use in European settings (Eurostat

2005). Scales for measuring economic welfare and well-being were also reviewed and suitable measures were included in the questionnaires to estimate the intangible economic impact of FAs (Kahneman, Diener, and Schwarz 1999; Veenhoven 2004; Boarini, Johansson, and d'Ercole 2006).

No validated instrument to measure the costs of FAs was discovered. However, a questionnaire designed and validated to measure the costs of illness for patients with early inflammatory polyarthritis (Cooper et al. 2003) provided a starting point for the FA questionnaire; it was revised by removing all reference to inflammatory polyarthritis and adding questions about FAs.

A wide range of scales were found, which could be used to measure the intangible impact of FAs. It was decided to include both preference-based scales for valuing health states (EQ-5D) and scales of subjective well-being measuring feelings of happiness.

The EQ-5D questionnaire has been used widely to assess health-related utility. The EQ-5D consists of five dimensions, associated with different aspects of health. Responses to these items have been converted to a health utility score between 0 (death) and 1 (perfect health) (see Brooks 1996; Dolan 1997). The EQ-5D is available in validated local language versions with local estimates of population utility weights across Europe. This scale has also been validated for use in the United States. Measures of welfare or utility specific to health status include the five-point perceived health status scale, which is used to indicate an individual's health-related well-being (see among others Wanamethe and Shaper 1991; Cutler and Richardson 1998; Gerdtham et al. 1999). This scale was included in the pilot questionnaire.

To assess subjective well-being of income, the "income evaluation scale" was used: to measure the individual welfare associated with household income respondents are asked to report their net income, then state what level of income they consider to be very bad, bad, insufficient, sufficient, good, and very good for them. They are asked to write an amount on a line next to each of these categories. After scaling the verbal qualifications on the [0, 1] evaluation scale, a normal distribution function is fitted to the logarithms of the reported incomes. This way, the evaluation of the household income can be assessed and the average income compensation for welfare differences across cases and controls can be computed (for overviews, see Kapteyn and Wansbeek 1985; Van Praag and Frijters 1999; Van Praag and Ferrer-i-Carbonell 2004).

The Cantril ladder (Cantril 1965; Veenhoven 2004) captures subjective well-being as feelings of happiness with one's overall life and comprises a visual analogue scale yielding values between 0 and 10, asking individuals to

rate their quality of life with 0 indicating the worst conceivable and 10 the best conceivable life. These scales are generic and can be used to compare results of cases and controls.

Severity of FA symptoms might have an economic impact (De Blok et al. 2007). FA symptoms range from uncomfortable skin rashes to life-threatening anaphylactic shock. The Mueller scale (Mueller 1966) had been used by health professionals to assess the severity of symptoms of patients suffering from allergic diseases; it makes a distinction between four gradations; I is very mild, II is mild, III is moderate, and IV is severe (see Mueller 1966, 1990; Ewan and Clark 2001; Clark and Ewan 2003; Brown 2004).

Finally, a review was conducted to assess if any further material had been published on measuring costs of FAs since 2004 (see Appendix SA2).

Focus Groups

Focus groups were conducted in the United Kingdom and the Netherlands to assess whether the chosen measures of economic costs, welfare, and well-being were meaningful to people with FAs, using the grounded theory approach (see Glaser and Strauss 1967; Strauss and Corbin 1990). In the United Kingdom, 10 participants with diagnosed FAs (six adults, three parents of children with FAs, and one partner of a person with FAs) attended three separate focus groups (five attended the first, one attended the second, and four attended the third). In the Netherlands, 18 participants with self-reported FAs took part in two separate groups (11 attended the first and 7 attended the second).

An expert panel of researchers and clinicians developed a topic guide for the discussions (including sociologists, health economists, consumer psychologists, nutritionists, and food allergists). In each group, there was a facilitator, an expert observer, and a note taker. The data collected in each country were analyzed by two different sets of researchers. The findings were distributed to and discussed with the panel of experts; consensus about interpretation was achieved before the development of the pilot questionnaire.

Participants were encouraged to speak freely about their experiences with FAs. They were also asked to complete a prototype questionnaire while being observed by researchers. The time taken to complete the questionnaire was recorded. They were asked to annotate the questionnaire with any comments they had, to raise questions if they did not understand items, and to discuss their experience of completing the questionnaire. In-depth cognitive interviews were carried out with two young people with FAs (age 18 and 21), one mature adult with FAs, and two parents of children with FAs. The

discussions were tape recorded and transcribed. Feedback from the interviews and annotations on the questionnaires were analyzed to assess whether participants had any difficulties in answering questions.

The group discussions highlighted many new themes and concepts. Participants discussed experiencing difficulties with a number of significant life events. For example, a parent said she had to give up her job because she needed to be on standby at all times in case her child had an anaphylactic shock. Another parent felt she “had to put her life on hold because the needs of her child came first.” A mature adult said that she had lost several jobs due to her FA and the amount of time taken off for sickness and for treatment. She also said she had found it impossible to sustain a relationship and felt that even if she did meet a life partner she would not want to have children, as she feared passing on her poor immune system.

Parents of young children (those aged under 10 years old) worried about their children playing with others who might have consumed or touched the food allergens to which their child was sensitive. Parents also reported concerns that their children could not take part in the sporting activities they wanted to as a result of their FA (see De Blok et al. 2007 for further discussion on this topic). A question about significant life events was therefore included in the economic impact pilot questionnaire, ensuring that a tick box was provided for each of the issues, which arose in the groups. In addition, an “other” option was included with space to allow the respondent to specify additional significant life events.

Definitional problems were highlighted when observing participants completing questionnaires and in the in-depth interviews. For example, it was noticed that young adults were providing details about the costs of leisure activities and food shopping of girl/boyfriends living in separate households in questions relating to partners or spouses. This implied that a more precise definition of what constituted a household was required in the information sheet, and that household composition questions were also required. The U.K. census definition of household was therefore added to the information sheet. Demographic questions in the opening section of the questionnaire were refined such that details of all the household members were requested, and in the final part of the questionnaire respondents were asked about living arrangements (e.g., do you “live alone,” “with a partner or spouse,” “with children,” or “with parents”).

The Mueller (1966) question contained medical terminology to describe symptoms, which participants found difficult to understand. Therefore, the medical terminology was adapted to lay language.

A further problem was highlighted concerning the use of the standard question about health resource use, restricting the time period to 3 months before the survey (used to maximize participant recall). Parents of children with FAs, found this question acceptable, as they frequently take up health care for their children (for FA-related problems and for childhood illnesses and vaccinations), whereas young adults, who tend to use health services less frequently, did not find this question meaningful. Some stated that they only utilized services once every 2 years to visit their FA specialist. To get a full measure of health resource use, we added a new question about frequency of health care use to the pilot version of the questionnaire (see Appendix SA3, Question 8 of the final version of the questionnaire for adults).

Participant took between 25 and 30 minutes to complete the questionnaire. There were no significant differences depending on whether the respondent was a young or older adult or a parent of a child with FAs.

Pilot Surveys

Cost of illness surveys are criticized because there is often an absence of counterfactual data, which could provide an estimate of added costs of the condition under investigation (Cooper et al. 2003). We aimed to redress this by developing and testing a generic questionnaire, which could collect comparable data from a cases group (with FAs) and a control group (without FAs). Surveys were conducted in the United Kingdom and the Netherlands. Table 1 summarizes the types of costs included in the questionnaires.

Demographic and income questions were included in the questionnaire to categorize individuals and to provide a basis to value the time spent shopping, using health services, and providing informal health care. The aim was to achieve samples of 50 cases (adults and parents of children with FAs) and 50 controls (households where adults and children did not have FAs) in each country. These numbers were necessary for meaningful analysis.

Samples of cases were recruited using media advertising. In the Netherlands, 92 people with self-reported FAs took part in the survey (63 adults with FAs and 29 parents of children with FAs). In the United Kingdom, 86 people with self-reported FAs took part in the survey (66 adults with FAs and 22 parents of children with FAs). Different methods were used to recruit control groups in each country. In the United Kingdom, a control group was obtained by mailing out a questionnaire to a random sample of 300 people in the Norfolk population (drawn from the Norfolk Electoral Roll). In the Netherlands, food-allergic participants were asked to recruit a control respondent

Table 1: Categories of Costs of Food Allergies for Individuals and Households

<i>Type of Costs</i>	<i>Individuals/Households</i>
Direct	Travel costs Hospital admissions Cost of medication (prescribed, OCM, and alternative) Cost of help with domestic duties Cost of food and leisure Lost earnings
Indirect	Lost productivity, restricted activity days Reduction in human capital Time spent on seeking health care Time spent on information seeking Lost leisure time
Intangible	Health-related quality of life Physical and emotional well-being Income evaluation Well-being

OCM, over-the-counter medication.

from friends, relatives, or neighbors living in a household similar to their own. For instance, if they were married with two children they were asked to invite a family with two adults and two children, but with no food-allergic members, to complete a questionnaire. Incentives were offered to encourage people to respond to the survey. In the United Kingdom, respondents returning a completed questionnaire were entered into a prize draw for £50. In the Netherlands, respondents were paid around 10 euro on receipt of a completed questionnaire. A cover letter was enclosed with the questionnaire emphasizing the importance of this research, explaining how to complete the questionnaire, and detailing the incentives for returning a completed questionnaire. Ethics approval was granted in both the Netherlands and the United Kingdom.

Pilot Data Analysis

Data Analysis and Quality Testing. The Statistical Package for Social Scientists (SPSS) was used to analyze the survey data. Data were entered by a research assistant and checked independently by a different researcher for accuracy, comparing the data entered to the questionnaire responses. Frequencies of each question were run to check for data entry errors, outliers, and to derive the item response rate. Tests of internal logic were conducted by running cross-tabulations to ensure that data had been entered into the correct

variables. Where errors were identified, they were corrected. The mean average and standard deviation for each cost for each group were calculated. Significance testing was not applied in the analysis of the pilot study owing to small sample sizes and unrepresentative sampling.

Derivation of Cost Variables. New cost variables were constructed from data provided by respondents and published unit costs to estimate annual direct, indirect, and intangible costs of FAs for individuals, households, and society. Indirect costs for individuals and households were derived from the amount of time individuals (the respondent, or their child, and, where applicable, the person[s] accompanying them) spent visiting or being visited by health professionals (including time taken to travel to the site of care, time spent waiting to see health professionals, and time spent in consultation with health professionals). Time spent visiting those in hospital was also included in the calculation of personal and household indirect costs. Time was valued using the midinterval of the reported banded net income of respondents and their partners (where applicable). Where respondents or partners reported that they were in paid employment, but did not report their income, the national average wage for the Netherlands and the United Kingdom was substituted (CBS 2006; Office of National Statistics [ONS] 2006, respectively). Where respondents and/or partners were not in paid employment, the national minimum wage for the Netherlands and the United Kingdom was used to add a monetary value to their time (Ministry of Social Affairs, the Netherlands 2006 and Department for Trade and Industry, UK 2006). We used the minimum wage as an estimate of the opportunity cost of time of people who were not in paid work on the assumption that their alternative activities would be at least valued at that rate. This assumes that they made the positive choice about their time and that they could work for the minimum wage. Of course this degree of choice would vary depending on unemployment rates. In this case, the social opportunity cost of the forgone activities would depend on the social value of lost informal production or leisure, which we could not know from this research. The implications of using this measure rather than the national average wage are discussed below.

Costs of health care were calculated based on reported use of health services and on who paid at the time of use. The degree to which the costs are borne by the state varies according to the national health economy. In the United Kingdom, the vast majority of people are entitled to free health care at the point of delivery under the National Health Service (NHS), although

there are some charges and some exemptions from charges especially for prescriptions. In the Netherlands, a social insurance scheme funds health care, and individuals may also have copayments. The questionnaire and analysis took account of these differences between health systems in three ways. Specifically, the analysis differentiated the categories of health care use included as options for responses, the unit costs of health care use (which need to match these categories), and the degree to which individuals are paying “out of pocket” for each of these services (as private or copayments) or are paying indirectly for their health care through insurance and/or tax.

In the Netherlands, the average costs for a visit to a GP, specialist, physiotherapist, and hospitalization were taken from Oostenbrink, Bouwmans, and Koopmanschap (2004) to estimate the costs of health care to the public sector. Costs of prescriptions in the Netherlands were taken from Stichting Farmaceutische Kengetallen (2006).

In the United Kingdom, the unit costs for NHS health care were taken from annual reported unit costs of items of health and social services (Curtis and Netten 2005), and the average cost of prescribed drugs was taken from national prescribing data from the NHS (NHS, Pharmaceutical Directorate 2004).

Pilot Results

The aim of the pilot survey was to further improve the questionnaire for use in a pan-European survey, aiming to make questions easier to answer, identify which questions were most appropriate and meaningful to respondents, and to reduce the size of the questionnaire by identifying redundant questions. In this section, we report how the pilot findings were used to modify the questionnaire.

Response Rates

The overall response rates for the pilot survey are set out in Table 2.

Quality and completeness of answers varied throughout the questionnaire. The revised question concerning frequency of health care use resulted in higher item response rates compared to the “standard” version of the question (both were asked at the pilot stage). For instance, 90 percent gave an answer to the question about frequency of visiting the family doctor, whereas only 51 percent answered the standard question about number of visits in the last 3 months. Some respondents wrote in different frequencies of use of health services to the options available in the pilot questionnaire. The next version of

Table 2: Distribution and Response Rates of Samples of Cases and Controls Obtained in the United Kingdom and the Netherlands Pilot Survey of the Economic Costs of Food Allergy Questionnaire

	<i>Total</i>	<i>United Kingdom (Response Rate %)</i>	<i>The Netherlands (Response Rate %)</i>
Total	187	91	96
Households with food allergy	125	60 (70%)	65 (71%)
Household with no food allergy	62	31 (10%)	31 (36%)

the question was revised to include finer bands for frequency of use and an option for “never” was added (see Q8, Appendix SA3). The standard question about health service use was omitted to reduce respondent burden. Respondents were asked to give an estimate of the number of minutes they spent waiting for and meeting with health professionals. Many answered with a range of times (such as “between 5 and 10 minutes”). This question was adapted to give categories with time “bands,” requiring a simplified tick box response.

There was a low response rate in the United Kingdom to the income evaluation question (Van Praag and Ferrer-i-Carbonell 2004). In the U.K. version of the questionnaire, respondents were not instructed to write an amount on each line next to the options, which asked them to assess what level of income would be very bad, bad, insufficient, sufficient, good, and very good. This instruction was included in the final version of the questionnaire.

Severity

The question on severity of symptoms (addressed to allergy sufferers only) was answered by all food-allergic respondents; this question was further simplified by grouping the symptoms into four boxes, in groups according to level of severity, requiring a maximum of four ticks rather than the possibility of up to 20.

Travel

The majority of respondents traveled to health professionals in a car, on foot or bicycle, or on the bus or train. The question was changed to ask how the respondent (or their child) usually traveled to health professionals and tick box answer options were provided for either “car,” “public transport,” “walk/cycle,” “other,” or “not applicable.”

Suitability for Cases Versus Controls

To increase the relevance of the questionnaire for those without FAs, all reference to FAs was removed from the title of the questionnaire and “not applicable” options were added to questions specifically about FAs. The pilot survey included open questions and “other, please specify” options. Two new significant life events were included in the revised questionnaire: problems with relationships, and restrictions on social life. As the pilot questionnaire did not collect this information for individuals without FAs, it was not possible to make comparisons between food-allergic and nonfood-allergic individuals at the pilot stage. It was decided that where significant life events had a measurable economic cost, it would be of value to collect this information from individuals without FAs. Therefore, this question was further adapted in the final questionnaire to a generic form asking whether the respondent had experienced any significant life events as a result of illness.

Economic Impact

Table 3 sets out a brief summary of the differences in direct and indirect costs for households with and without food-allergic members. The analysis also highlighted differences in quality of life, with those with FA reporting lower health utility scores (EQ-5D), lower levels of satisfaction with life (measured by the Cantril Ladder), and lower income (responses to the Income Evaluation

Table 3: Annual Direct and Indirect Costs for Households and Direct Costs for the Health Sector—Comparing Households with Food-Allergic Members and Households with No Food-Allergic Members (Price Year 2006, euro)

<i>Annual Costs</i>	<i>Self Report Food Allergies</i>	<i>Without Known Food Allergies</i>	<i>Difference*</i>
Direct costs for households (euro)	8,984	7,896	1,088
Standard error	472	662	
Health sector costs (euro)	464	190	274
Standard error	71	43	
Indirect costs for households (euro) [†]	9,269	6,698	2,571
Standard error	835	1,172	
Number	125	62	187

*Statistical significance of the differences does not reach conventional levels (95% confidence intervals for difference contain zero).

[†]The minimum wage was used to estimate the value of time for adults who were not in paid employment. If the national average wage had been used, the costs presented would have been 32% higher. This is likely to be explained by the high proportion of retired people responding to the adult survey.

question). More detailed analyses of the pilot results are provided in Voordouw et al. (2009).

DISCUSSION AND FUTURE PLANS FOR THE QUESTIONNAIRE IN FA RESEARCH

This paper has described the development of a questionnaire for measuring costs of FAs. To the authors' knowledge, no such instruments have been developed elsewhere. Focus groups provided important information, which helped to further refine the prototype questionnaire, particularly in terms of gathering information concerning significant life events and in patterns of health care use.

The pilot survey confirmed that the questionnaire produces plausible results and provides appropriate data to estimate costs for households with or without food-allergic individuals. However, the statistical significance of these findings is not reported in figures, as this was a pilot study not setting out to test the hypothesis of difference between groups. However, the figures presented enable us to estimate sample sizes necessary in the next stage of the study: we estimate that each center in the study will need to recruit at least 100 respondents in each of the case and control groups, to have power of 80 percent and confidence at 95 percent level to identify for center-based differences in costs between case and controls.

We recognized at the outset that health utility is not likely to be a sufficient measure for quality of life overall, as has been shown in studies of other chronic or intermittent illnesses, and therefore included other measures of welfare. In addition, a disease-specific quality of life instrument has been developed in parallel with our instrument (Flokstra-de Blok et al. 2008). We will have the opportunity to compare the results collected in samples of the same subjects using both instruments to assess the relevance of the generic measures used in our questionnaire to assess quality of life in FAs in the next stage of the study. Using the minimum wage rather than the average wage to calculate the opportunity costs of those not working in paid employment might have led to an underestimate of the additional societal costs of FAs; sensitivity analysis will be done in the next stage of the study using the average wage in place of minimum wage.

The questionnaire was simplified and reduced by creating closed questions with tick box responses, removing unnecessary questions, and including simple filter instructions to skip nonapplicable questions.

This questionnaire is available to be used to measure the costs of FAs (and with modification other chronic illnesses) to individuals and households and to evaluate models of health service delivery in many different settings and countries. It will prove valuable in evaluating new therapies for treating allergic patients, such as the immunotherapy developed in Cambridge by Clark et al. (2009). The questionnaires have been adapted for application in Europe, Australia, and India and the method of data collection has been adjusted to suit the culture and health setting in each country. It would be necessary to culturally adapt the questionnaires for use in the United States to make it suitable for application in the U.S. health system and among the diverse communities and to include at the analysis stage valid EQ-5D weights for the United States.

All versions of the questionnaires, along with an instruction manual, can be obtained from <http://www.euoprevall.org>. The authors hope that the questionnaires will be used in future research and would be grateful if users would register their interest in this and acknowledge the source.

ACKNOWLEDGMENTS

Joint Acknowledgment/Disclosure Statement: This study is being conducted within the collaborative research initiative EuroPrevall, an integrated project funded by the European Commission under the 6th Framework Programme (FOOD-CT-2005-514000).

Disclosures: This paper was presented at the U.K. Health Economist Study Group in January 2008 and at the 7th European Conference of Health Economics in June 2008 in Rome. The abstract has recently been published in ECHEROMA book of abstracts available at <http://www.echeroma2008.eu>.

Disclaimer: None.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.

Appendix SA2: Literature Search for Instruments to Measure Costs of Food Allergy.

Appendix SA3: Household and Individual Costs of Living, Health, and Illness.

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