HEALTH ECONOMICS GROUP
Faculty of Medicine and Health
Norwich Medical School

UEA
University of East Anglia

Social and economic costs of food allergies in Europe: translation and trans-cultural adaptation into different languages of a questionnaire to measure costs and health utility

Margaret Fox[1], Inmaculada Cerecedo [2], Belén de la Hoz Caballer [3], Javier Zamora[4], Ewa Rokicka[5], Pawel Starosta[5] , Nikolaos G. Papadopoulos[6], Katerina Lagara[6], Miranda Mugford[1]

[1] University of East Anglia, Health Economics Group, Faculty of Medicine and Health Sciences, Norwich, NR4 7TJ, UK
[2] Sección de Alergología. Servicio de Medicina Interna Hospital del Sureste. Arganda del Rey. Madrid. Spain.
[3] Servicio de Alergología. Hospital Universitario Ramón y Cajal. Madrid. Spain. [4]Unidad de Bioestadística Clínica. Hospital Universitario Ramón y Cajal. CIBER de Epidemiología y Salud Pública (CIBERESP). Madrid.
[5] University of Lodz, Institute of Sociology, Lodz, Rewolucji 1905 41/43, Poland
[6] Allergy Dpt, 2nd Pediatric Clinic, University of Athens

Email addresses:

MF: m.fox@uea.ac.uk or Margaret.fox01@btinternet.com
IC: inmaculadacerecedo@gmail.com
BHC: bhozcaballer@gmail.com
JZ: javier.zamora@hrc.es
ER: rokicka@uni.lodz.pl
PS: socwim@uni.lodz.pl
NP: ngp@allergy.gr
KL: catlagara1@yahoo.gr
MM: m.mugford@uea.ac.uk
ER: rokicka@uni.lodz.pl
PS: socwim@uni.lodz.pl
NP: ngp@allergy.gr
KL: catlagara1@yahoo.gr
MM: m.mugford@uea.ac.uk

ABSTRACT

BACKGROUND

With the growth in international comparative research in the field of health economics, new tools to collect comparative data from disparate countries are required to measure and compare the costs of illnesses.

METHODS

A multistep approach was used to translate an English questionnaire to measure the costs of food allergies across 12 European countries, using WHO guidelines as a minimum standard. Greek, Polish and Spanish translations are presented as case studies. Survey response rates and item non-response rates were analysed to evaluate the process.

RESULTS

Questionnaires were adapted to reflect different health professions and health settings in each country. Spain achieved the highest response rate (85%) and lowest item non-response rate (85%; 1.52%) compared to Poland (68%; 4.97%) and Greece (38%; 10.64%). Spain implemented a more complex translation protocol than Poland and Greece.

CONCLUSION

More complex translation protocols yield better results, but this paper concludes that good channels of communication between originators of questionnaires and translators is most effective way of ensuring good quality outcomes.

BACKGROUND

Food allergy (FAs) is an important health policy issue in Europe and developed countries [1]. FA is an adverse reaction to food mediated by the immune system[2]. It is estimated that up to 8% of children and 4% of adults may suffer from this condition[3]. Moreover, up to 25% people believe that they or their children suffer from FA, increasing downstream consequences, such as diet restrictions[4]. Children with FA tend to overcome their problem, but some allergies persist into adulthood. Symptoms of FAs can vary from very mild to severe with life-threatening anaphylaxis. FA is probably the most common cause of allergy related mortality[5].

There is no cure for FA, strict avoidance of the allergens is the only method of managing this disease. However, this is associated with a constant risk of accidental ingestion of allergens, creating uncertainty, impinging on the quality of life, cost of living and use of health resources [6,7,8,9], but until recently there have been no tools to measure these costs. Miles et al[10] developed a framework to assess the socioeconomic impact of FA, including direct, indirect and intangible costs. Fox et al[11] used this framework to develop a questionnaire to estimate the costs of FAs to individuals, households and health sectors across Europe.

Questionnaires were designed to measure the impact of FAs in both adults and children. The survey was conducted alongside epidemiological and clinical studies[12] to collect data about the day–to-day cost of living of households and direct and indirect costs of seeking and using health resources. Health resource use was assessed by asking respondents how often respondents or their children visited family doctors, nurses in clinics or hospitals, specialists, dieticians, physiotherapists, and alternative therapists, how much time they spent travelling to, waiting for and

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consulting with health professionals; and whether they had been admitted to hospital in the previous 12 months. Out-of-pocket expenses for healthcare included costs of travelling to health professionals, paying for private healthcare (including private health insurance), and medication (including prescription charges and over-the-counter-medicine).

The source language for the questionnaires was English. In the initial stage of development the questionnaire was translated into Dutch, using forward and back-translation. Both the English and Dutch versions were tested in focus groups, in cognitive interviews and then in a case-control pilot survey in both the UK and the Netherlands[8,11]. The questionnaire was translated into other non-English languages for use in 12 European countries as part of the Europrevall Project[12, 13,14,15].

This paper uses the Spanish, Polish and Greek translations as case studies to describe to translation process. To evaluate the processes carried out in each country, the item non-response rates and the survey response rates are compared. These case studies provide a unique opportunity to compare the outcomes of translations of the same questionnaire using a core protocol, plus a variety of enhanced protocols.

AIMS AND OBJECTIVES OF THE TRANSLATION

The main objective of the research was to translate and culturally adapt a health economics questionnaire to measure the socioeconomic impact of FAs in Europe. The aim was to make the questionnaire psychometrically, contextually, semantically,

operationally and criterion equivalent for each country and so valid for comparisons of costs for households and individuals between countries[16]. We aimed to achieve:

- psychometric equivalence by adapting the language used to carry the same meaning in each country

- contextualisation by adapting the language to reflect the types of health professionals and health settings in the target country

- semantic equivalence by ensuring the questionnaire used colloquial language which was meaningful in the target country

- operational equivalence by developing a standardise protocol for administering the survey in each country

- Criterion equivalence by using scales, where possible, which had been tested and assigned country specific tariffs (such as the EQ-5D)[17].

METHODS
Protocol for translation

Academic and clinical researchers in Greece, Spain and Poland implemented the translation of socioeconomic questionnaire. The questionnaire had been developed in English in the UK using cognitive interviews[18] and focus groups with people with self-reported and clinically diagnosed food allergies. The questionnaire was translated into Dutch and tested using cognitive interviews and focus groups in the Netherlands. The questionnaire was back-translated into English and verified by the authors of the English version. The English and Dutch versions were tested in a pilot survey, the results are reported elsewhere[10]. Implementation of the translation of questionnaire into other non-English languages was coordinated and managed by the English authors, to ensure that the questions remained consistent across each language. The

UK coordinator met with local project managers in each country to provide training and supporting materials (consisting of written instructions and flow charts) to illustrate the translation protocol. The training followed WHO guidelines[19] for translating health questionnaires. However, collaborators were instructed to adhere to these guidelines as a core protocol for translation, and informed that they could enhance these subject to available resources. The Spanish and Polish translations took place in the target country as collaborators had resources available to fund to the translations of the questionnaire in situ. However, Greek partners had limited resources, therefore the Greek questionnaire was initially translated in the UK, overseen by the English authors of the questionnaire.

Recruitment of translators

An important aspect of assuring quality in the translation process is the recruitment of competent translators, therefore a standardised protocol for recruitment of translators was developed in the UK. The criteria for recruiting translators are set out in Table 1. Applicants were interviewed and scored systematically against these criteria.

Briefing translators

All translators were fully briefed about the objectives of the study and the translation. Forward-translators were asked to critically review the types of health professionals and the types of healthcare settings in the source version and amend if necessary to be meaningful to the target population. Translators were also instructed to use non-technical/medical language to translate the questionnaires. Back-translators were asked to convey the meaning of the forward-translation, but to back-translate as literally as possible and to discuss any ambiguities with the local project manager.

Translators were asked to discuss all changes with the local project manager, who in turn verified them with the English author.

Methods for evaluating the translation

The translations were evaluated by analysing the unit response rates (percentage of all returned questionnaires) and item-non-response rates (percentage of respondents not answering each question) to the main survey. The item-non-response rate can give an indication of the level of clarity, comprehensiveness and relevance of the question to respondents. All questions had a possible and mutually exclusive answer. Therefore it was assumed that participants had *chosen* not to answer unanswered questions. Responses were grouped into a binary variable scoring 0 if no answer was given and 1 if the question was answered. Chi square test for indifference, Cramer V and the Goodman and Kruskal tau proportional reduction of error measure were used for significance testing. Where the assumptions for Chi square tests were not met (i.e. cells containing < 5 observations) Fisher's exact test was conducted.

Ethics approval

Ethics approval was granted in each country from the following Ethic Committees:

Comite Etico de Investigación Clínica

Hospital Ramón y Cajal

Ethics Committee

P&A Kyriakou Children's Hospital

Prof. dr Przedzisław Polakowski, Przewodniczący (Chairman) Komisji Bioetycznej Uniwersytetu Medycznego w Łodzi,

RESULTS

Selection of translators

During the recruitment interview each translator was given a score against each of the selection criteria of 1 for poor, 2 for satisfactory, 3 for good and 4 for excellent. Table 1 shows the scores achieved by each translator for each of the criteria and the total score out of a possible maximum score of 24. The pass score was 18 out of 24. Translators were appointed if they met or exceeded the pass score.

The remaining results will be presented in two sections: 1) the translation process and 2) the analysis of the unit and item response rates.

Table 1 – Criteria and Selection scores for each Translator

Criteria	Greece		Poland		Spain		
	Forward-translator	Back Translator	Forward-translator	Back Translator	Forward Translator 1	Forward Translator 2	Back Translator
Scores							
Bilingual	3	3	3	3	3	4	3
Advanced level qualification in English	3	3	3	3	3	3	3
Mother tongue language of target translation	4	4	4	4	4	3	4
Extensive knowledge of target health service	4	4	4	4	4	4	4
Extensive knowledge of the UK health service	3	2	3	2	4	3	3
Experience of translating research instruments	2	2	4	2	3	2	3
Total score	19	18	21	18	21	19	20

1: Translation protocol for each language

As mentioned above the core protocol for translation was adhered to in each country, with enhancements made where necessary.

Polish translation

The Polish translation protocol strictly adhered to the WHO guidelines. The questionnaire was forward-translated by a native speaking health professional who had an in-depth understanding of the UK health service. It was back-translated was by an independent translator with equivalent experience to the forward-translator. The

forward translation was reviewed and tested in three cognitive interviews with patients with food allergies and all comments and difficulties were recorded.

Three cultural differences were identified in the cognitive interviews: differences in health resource use, patterns of food consumption and nutrition, and household division of labour. Polish respondents queried the relevance of questions about time spent waiting and consulting with health professionals. They also queried the relevance of including questions about shrimps, crabs, other seafood, avocado, soy and sulphites as they were not commonly consumed in Poland. Male respondents, had difficulties answering questions about food expenditures and amount of time spent shopping and cooking as they claimed they very rarely carry out these tasks. Women also found it difficult to estimate these times as they claimed these tasks were 'routine so they paid little attention to the time taken to complete them'.

The questionnaires were modified to take on board any comments, back-translated into English. The back translated version and findings of the cognitive interviews were discussed with the English authors. After careful consideration it was agreed that the questions regarding time spent seeking and using health resources, time and money spent on shopping and cooking were fundamental measures for an economic comparative analysis, so should be retained in the questionnaire, but that the concerns of Polish respondents would be taken into consideration during analysis. It was also agreed that although a selection of the food types listed in the questionnaire were not commonly consumed in Poland, that they should be retained to ensure all possible food allergies were covered. A final version of the Polish questionnaire was agreed.

Greek translation

As the Greek translation took place in the UK, it was important to use a method to ensure that the English author of the questionnaire was confident that the translation conveyed the correct meaning of the questions in Greek. The UK author employed native Greek speaking translators, who were also fully fluent in English and had a good understanding of both the Greek and the UK health services. The English author used cognitive interviews with translators to ensure the accurate and consistent translation of the Greek questionnaires. This enabled the English author to ensure the forward translator fully understood all of the questions in the English versions of the questionnaire and fully understood the objectives of the translation. The cognitive interviews with the back translator aimed to ensure that the questions had been interpreted correctly by both the forward and back-translator. The interview with the back-translator identified syntax and spelling errors, but more importantly highlighted a fundamental translation error. Although the forward translator had been instructed to use lay terminology to describe medical symptoms of FA, interviews with the back-translator revealed that the forward-translator had translated these symptoms into medical terminology. The English author instructed the back translator to revise the forward-translation of the questionnaire to rectify this and to amend any syntax or spelling errors. A second version of the Greek questionnaire was sent to the forward-translator for review. The coordinator and the forward-translator discussed changes and agreed the third version. A further level of verification was carried out by a panel of health experts in Greece, providing a critical review of the questionnaires. Version 4 was back-translated and reviewed by the coordinator. A final version was agreed and piloted with 10 Greek patients, who completed all questions and did not raise any concerns.

Spanish translation

The Spanish translation protocol was more complex than the Greek and Polish translations. The forward-translation was carried out by two independent translators. Each of the translators gave a score to each of the questions during the translation process to indicate its ease of adaptability (scoring each item on a scale of 0-10 to measure difficulty of adaptation). Questions were also classified into 3 groups: A) question which could be translated literally; B) questions where substitute words were required; C) questions where no equivalent or substitute word was available. There were 59 items in the questionnaire; 27 were classified easy to translate and falling into group A, being translated literally. Two questions were scored difficult and classified as group B, requiring substitute words; for example, questions about lost earnings due to seeking healthcare were categorised as moderately difficult to translate, as there was no consensus about the term "lost earnings"; one translator used the term "decreased" and the other used the term "losing to spend". Thirty questions were scored as difficult to adapt, but they were also classified as group B questions as they could all be adapted with substitute wording. These questions included those about types of healthcare settings and foods. For example Spanish respondents did not distinguish between University Hospitals and General hospitals. Foods which are common causes of allergy in other countries (e.g. celery) are rarely consumed in Spain and almost never reported as a food allergen, whereas vegetables in general have been reported to cause allergies.

Each translation was annotated with the translators' comments and their recommendations for substitute words. The translated questionnaires were reviewed by a panel of experts comprising two social scientists and two allergists. Regarding

the example mentioned above, the panel of experts decided that using the term "decreased" conveyed the more accurate meaning of the question about lost earning as a result of seeking healthcare. The questionnaire was then tested on patients before the back-translation was conducted.

All comments and suggested amendments were discussed with the English authors. It was agreed that the category of University Hospital could be removed from the questionnaire as this was meaningless to Spanish respondents and increased the risk of error; the term 'General Hospital' was therefore used. All food types were retained to ensure all allergens were included and in addition, a category of vegetables was included. A final draft version of the questionnaire was agreed and tested in a pilot survey of 23 respondents with food allergy (adult version N=6; parent version N=17). All questions were answered by pilot survey respondents and no difficulties were reported.

2: Results of non-response rate analysis

To evaluate the translation of each of the questionnaires the survey response rate to the main survey and the item non-response rate in each of the case study countries are presented. In Spain 85% of those given a questionnaire returned a completed questionnaire, as did 68% of those in Poland and 38% of those in Greece. There was no difference in the response rate for cases and controls (as defined above) in Poland and Spain. In Greece there was a significant difference in the response rates for cases and controls, with 55% of cases returning a questionnaire compared to 21% of controls (p-value .0001).

The next section presents the results of the analysis of the item non-response rate to a selection of key questions. In Table 2 the item non-response rates for questions about FAs apply only to those in the 'case' groups; all other questions apply to both groups of respondents. The mean average non-response rate for each country is set out in the last row and the average non-response rate for each question is set out in the penultimate cell of each row.

Table 3 – Item non-response rate to a sample of key questions in surveys in Greece, Poland and Spain

|	Greece % (N=85)	Poland % (N=647)	Spain % (N=606)	Average non Response Rate %	Significance P value
Any member unable to do Household tasks	9.5	22.6	1.3	12.1	.0001
Household Income	27.4	9.4	7.8	10.4	.0001
Income welfare	26	8	6	9.8	.0001
Time spent cooking	17	6	2	4.8	.0001
Money spent on food	12	5.7	1.6	4.3	.0001
Life events	20	5	1	4.2	.0001
Time spent shopping	15	5	.5	3.8	.0001
Respondent Health status	13.1	5.7	.3	3.8	.0001
Education level Respondent	8	5	1	3.1	.0001
Food allergens for adults	9	2	2	2.5	.093*
Cost of travelling to healthcare	13.1	2.5	0	2.0	.0001
EQ5D	4.8	3.1	.2	1.9	.0001
Age of onset	0	1.6	2.3	1.6	.869*
Visits to Health Professionals	6	2	0	1.4	.0001
Food allergens for children	-	2	2	1.8	1.0
Average non response	10.64	4.97	1.53	3.92	

\- means the sample of children was too small for analysis

Chi square, Cramer V, Phi, and Goodman & Kruskal (in each test the same p value was found and is presented in the last column) tests were used to assess significant differences. Where the assumptions for Chi square test were not met (i.e. less than 5 observations in each cell) the Fisher's exact test was used [this is denoted with *].

Greece had highest mean item non-response rate and Spain had the lowest.   Question 25 (Q25: *Was any member of the household unable to carry out household tasks in the previous month?*) had the highest average non-response rate, this was significantly higher in the Polish survey (p-value .0001).   The income-welfare question (which asks people to indicate a level of income for their household that ranges between "very bad" to "very good") also had a high non-response rate. Greece had the highest non-response rate to the question about household income. The question about the types of foods allergens were answered by the vast majority of respondents in the surveys in Poland and Spain, yet nearly 10% of Greek respondents declined to answer this question.   Also, the vast majority of respondents in Poland and Spain answered the questions about time spent shopping and cooking and about money spent on food, whilst a large minority in Greece declined to answer these questions. A large minority of Greek respondents also declined to answer the question about how health and illness impacted on significant life events (20% p-value = .0001).   The questions about health resource use, cost of travelling to seek healthcare, the age of onset of FA and the symptoms experienced when having an allergic reaction to foods were answered by the vast majority of respondents in each country, as was the EQ-5D question.

To assess whether the item non-response rate was affected by the positioning of questions in the questionnaire, the magnitude of the item non-response rate for each question was plotted against the position of each question in the questionnaire, and are presented in Figure 1.

Figure 1 - Magnitude of item non response rate for each question
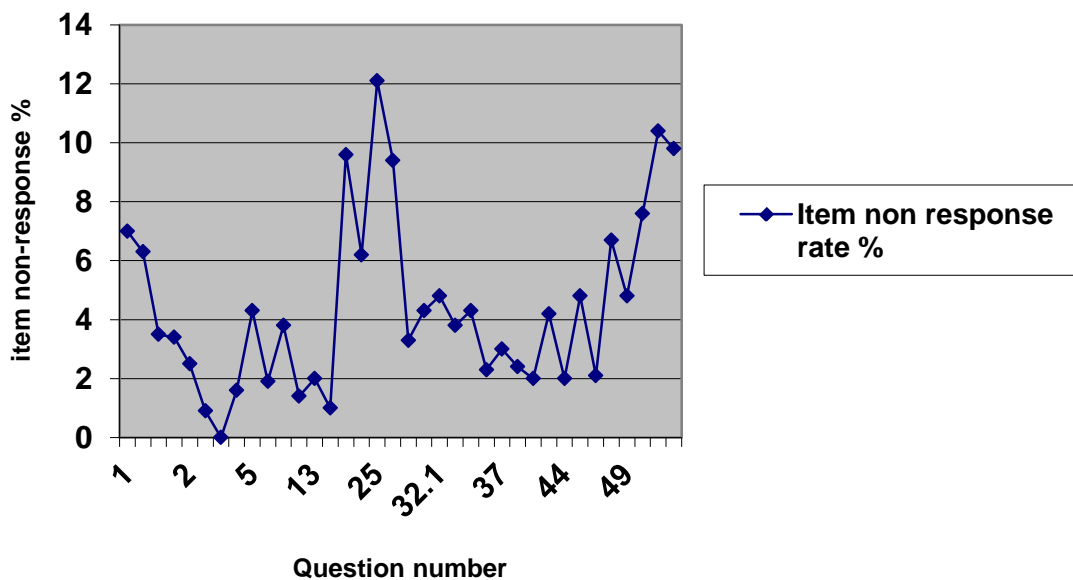
The association between the position of the questions and the magnitude of the item non-response rate was calculated in SPSS using a Kendall's tau_b. A significant but weak association was found between the positioning of the questions and the magnitude of the response rate, with a trend that the item non-response rate increased as the questions progressed. The coefficient was .225 and p-value of .077. This association was no longer significant when item non-response rate for the two questions about income were excluded from the analysis (coefficient = 0.077 and p-value .556).

DISCUSSION

There is currently no gold standard for the process of translating and culturally adapting questionnaires for use comparative analysis of the socioeconomic costs of long-term conditions in disparate countries; translation of such questionnaires is considered a 'science under development'[16]. This is the first questionnaire available to measure the direct, indirect and intangible costs of FA in European languages. This paper has described the protocol used for translation of the original English instrument, to Greek, Polish and Spanish. The results show that outcomes varied across translations of the questionnaire. There can be many explanations for this variation, including design issues, such as the number and positioning of questions in the questionnaire; the extent to which language and cultural differences can be bridged, the resources available to translate questionnaires and implement surveys, and the protocols for achieving these objectives. However, Figure 1 suggests that the item non-response rate is only weakly associated with the design of the questionnaire.

Feedback from the cognitive interviews with the Greek translators and respondents in the pilot surveys in each country found that most of the questions in the questionnaire could be either translated literally or could be substituted with readily available words. The item non-response rate analysis suggests that there was no detrimental impact of retaining a consistent list of foods, and that the Polish respondents were able to answer questions about time spent seeking healthcare, shopping and cooking. Male respondents in Poland were, despite the reservations highlighted in the pilot interviews, able to answer questions concerning domestic duties, such as estimations of how much time was spent cooking and shopping and how much money was spent on food. However, Polish respondents were least likely to respond to the question about carrying out household tasks during the last month.

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Although some of the respondents participating in the pilot testing of the questionnaire in Spain and Poland questioned the reasoning behind collecting information about the costs of travelling to seek healthcare, the vast majority of respondents in these countries answered this question. Respondents in Greece were less likely to do so.

Contextual adaptation of the questionnaire presented the anticipated challenges of adapting a questionnaire developed in one country for use in several countries. In particular, adaptations were necessary to reflect the diversity of the with different health services available in each country.

The most significant differences were found in the high item non-response rates in Greece; the Greek survey had the highest item non-response rate in 12 out of the 13 key questions presented in Table 2. This might be related to the reduced availability of resources to translate the questionnaire and implement the surveys in Greece compared to those available in other countries. Unlike Polish and Spanish clinical partners collaborating with the economic FA surveys, Greek clinical partners did not have the support of a local project team with resources to translate the questionnaire, pilot test it, adapt it accordingly and implement the survey. Nor did they have the resources available to the Polish and Spanish project teams to attend all of the face-to-face meetings in workshops with the coordinators of the survey to undertake training and receive guidance about the translation process and the implementation of the survey. Also, in Spain and Poland, unlike Greece, resources were available to send out reminders to those failing to respond to the survey.

CONCLUSIONS

The translation and adaptation of a questionnaire for use across culturally and economically diverse countries was labour intensive. A much higher response rate was achieved in Spain and Poland compared to Greece. This can probably be explained by the better channels of communication between collaborators in Spain and Poland and the UK coordinator and the greater resources available in these countries. It is possible that the more complex protocol used in Spain explains the higher response rate achieved; however, the process in Poland was less complex and similar item response rates were achieved. The low response rates in Greece might be explained by lack of resources for adapting the questionnaire in the source country. Therefore it can be concluded that the quality of translations can be improved by using a more complex translation protocol. However, this paper has highlighted that good channels of communication between the original authors of the questionnaire and those translating the questionnaire is probably the most significant factor for ensuring good quality outcomes.

COMPETING INTERESTS
None.

AUTHORS' CONTRIBUTIONS

MF developed the protocol for the translation of the questionnaires, was responsible for the overall management and evaluation of the translation process, analyzed the reports of the translation process in each country, analyzed the response rates to evaluate the questionnaire, drafted the paper and took responsibility for submitting it for publication.

IC and BCH managed the translation in Spain, reported the process to MF and contributed to drafting the paper

JZ prepared the data for analysis and provided statistical advice, he also commented on the final draft of the paper

ER and PS managed the translation process in Poland and drafted a full report of the process which provided data and text for the paper; they also commented on the final draft of the paper

KL and NGP reviewed the translation of the Greek questionnaire and further developed and piloted it in Greece. They provided a full report of the process which provided data and text for the paper; they also commented on the final draft of the paper.

Miranda Mugford was the principal investigator for the Economics Work-package in Europrevall and was primarily responsible for the design of the project. She contributed to the development of the translation process, made comments on the original outline of the paper and on the final draft of the paper.

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Additional files

Additional file 1 – Adult version of the questionnaire - English
This is a Word file

Additional file 2 – Adult version of the questionnaire - Greek
This is a Word file

Additional file 3 – Adult version of the questionnaire - Polish
This is a Word file

Additional file 4 – Adult version of the questionnaire - Spanish
This is a Word file