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An eHealth Approach to Reporting Allergic Reactions to Food and Closing the Knowledge Gap

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Abstract

There is an important knowledge gap in food allergy management in understanding the factors that determine allergic reactions to food, in gathering objective reports of reactions in real time, and in accessing patients' reaction-histories during consultations. We investigate how eHealth methods can close this knowledge gap. We report experiences with an online tool for reporting allergic reactions that we have developed as a web application. This application has been successfully validated by participants from Ireland and the UK, and is currently being used in a pilot where participants report allergic reactions in near-real time.

Keywords:

E-Epidemiology; Recall Bias; Web-based Reporting; Allergic Reaction; Food Allergy; Personal Health Record; Self-care.

Introduction

Allergic disease is a growing health risk [1],[2], while its management by clinicians and patients is challenging [3],[4],[5].

Food allergy has reached epidemic proportions in developed parts of the world [6],[7] with up to 20 million European citizens suffering from food allergy [8] and reports of increasing prevalence in developing countries [9]. The reasons for such an increase are not well understood. The estimated worldwide prevalence of food allergy varies according to age with 3-8% reported prevalence among children and 1-3% among the adults [10]. Unsurprisingly, food allergy is a leading cause of anaphylaxis seen in emergency departments across the USA and UK [11],[12].

We can identify the following problems in food allergy:

1. There are gaps in current scientific and societal knowledge, in terms of linking food allergy complaints from patients to evidence. Correlates of risk perception, risk taking behaviours, and psychosocial aspects have been largely overlooked in the literature of the topic.
2. During typical clinician consultations with food allergy patients, the clinician has only a short time (e.g., 20 minutes), and normally no access to consistent detailed information about the patient's previous reactions. Inexperienced doctors may misinterpret both mild and severe allergic reactions. Also, patients describing previous reactions tend to exhibit a recall bias, recalling better the more severe reactions, and failing to report the mild reactions.
3. Food manufacturers often don't have post-marketing information on the incidence of accidental allergic reactions due, for instance, to cross contamination as there is no system in place for reporting real-time allergic reactions in the community setting.

Scientific aim and objectives

Our aim was to improve the capture of objective information on accidental allergic reactions to food in order to address the knowledge gap in food allergy.

Our primary objective was to develop a system that can be used by food allergy sufferers to report information about suspected allergic reactions. This system is intended for collecting data in validation and pilot studies as part of the iFAAM EU FP7 project (integrated approaches to food allergen and allergy risk management), seeking the factors related to food reactions. Data will be integrated into the iFAAM informatics platform Allerg-e-Lab.

Our secondary objective was for this system to be developed as a prototype reporting tool that could be used by clinicians and patients to report and view previous allergic reactions in a clinical context.

Relationship to similar existing systems

There are a number of spontaneous reporting systems for reporting adverse events in areas of blood transfusion [13], medical equipment, drugs or tissues [14],[15], and foods [16]. These tend to be nationwide systems for the capture of reports of adverse reactions for regulatory reasons where there may be a mandatory requirement to enable adverse events to be reported; they never have a clinical function. In contrast, we are developing a system with eventual application in clinical consultations, giving clinicians access to patient-reported historical allergic reactions.

Our approach has been to understand food allergy and the context of reactions as opposed to just a context of foodstuffs (i.e. a register of products leading to adverse events). We capture a range of factors specific to food allergy, photos, food sample descriptions, and a questionnaire regarding the reaction.

Methods

Developing the system requirements

The stakeholders/users of the system are:

- clinicians, researchers, nurses, and study staff at University Hospital South Manchester (UHSM), UK;
- research staff and clinicians at University College Cork, Ireland (UCC);
- study participants recruited online, through the Anaphylaxis Ireland website, the Anaphylaxis campaign website, and UHSM allergy clinic.

The system requirements were developed in an iterative cycle of discussing requirements, implementing a draft solution, and incorporating feedback from stakeholders into refinements.

Questionnaire structure

In order to capture necessary information about food allergy reports from participants, to address our primary objective, the allergic reaction in the community (AlleRiC) questionnaire instrument was developed. This took place between March-October 2013 following 16 focus groups of adults and children diagnosed with food allergies. The instrument was developed in Ireland and the United Kingdom by experienced clinicians and researchers with an active contribution of patients' organisations. Transcripts were then analysed using the grounded theory approach, which involved coding and categorising codes into emergent themes. Items selected from the themes found in the transcripts were taken verbatim and then rephrased into a question format. Items were constructed to reflect the most prevalent characteristics and circumstances of food-allergic incidents as experienced in the real world.

Three experts in the field were consulted in person and via an exchange of e-mails; all disagreements were dealt with by negotiations till consensus was reached. Finally, the recent relevant literature in the field was reviewed to triangulate the above contributions.

In total there are 81 question items including conditional questions. When the participant first logs in they are asked to complete four enrollment questions. The incident questionnaire is then answered for each future reported reaction.

These questions were based on what consumers themselves told us were their main concerns related to the aims of the study, so are grounded in everyday lives and behaviours and therefore one aspect of good construct validity.

The questionnaire captures information about the following factors: subjective intensity measure (Figure 1), location and social context, food/meal/allergen details, physical and psychological symptoms, co-factors such as exercise, trip abroad, period, medication used, and follow-up, labelling and other allergen information, community and professional support, and additional comments.

Validation study

We carried out an initial feasibility study in the form of a validation study, to check that participants are able to use the system to report reactions. A separate group of adult patients diagnosed with food allergies in Ireland and the UK was recruited between December 2013 - February 2014 to evaluate the system by reporting an historic reaction. Participants were recruited online through charities that support food allergy sufferers: the Anaphylaxis Ireland website (www.anaphylaxisireland.ie), the Anaphylaxis Campaign website (www.anaphylaxis.org.uk), and UHSM allergy clinic.

Individual question items of the tool were psychometrically assessed via a novel Evaluative Scale (ES). ES was developed by researchers and patients to allow for the evaluation of five distinct aspects of the prototype questions: ease of understanding, reasonableness, usefulness, ease of answering, and clarity of instructions.

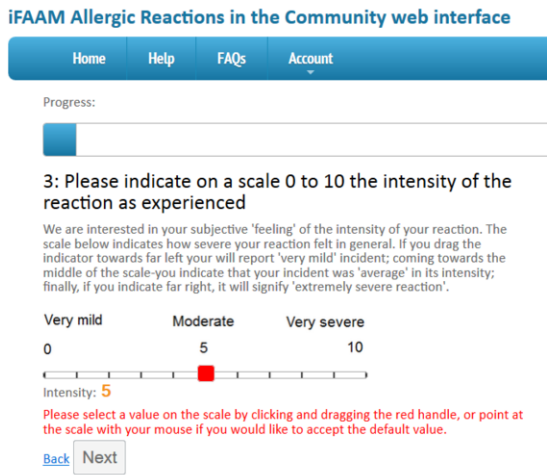

Figure 1 – Screenshot with reaction intensity question

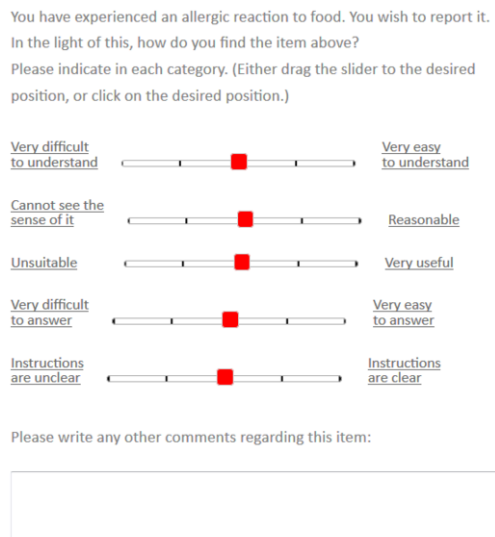

Figure 2 - Evaluative scale as implemented online

Figure 2 shows the evaluative scale as implemented in the AlleRiC system graphically.

ES uses a Likert-type response format on a five-point left-to-right scale range from "0" standing for "very negative evaluation" to "4" standing for "very positive evaluation".

Hence, each question item consists of the question, and the validation section of five drag and drop scales, and a textbox for comments on the question item.

Results

Requirements

Study participant requirements

Study participants need to use the system for three main tasks: 1) when using the system for the first time they should

complete the consent form if they are have not done so in a clinic, view training materials and complete the enrollment questionnaire; 2) if they experience a suspected allergic reaction to food, they will need to complete an incident questionnaire to describe their reaction, if available they can upload photos of skin symptoms or food; and 3) users should be able to access a list of their reported reactions by date, but not extract any data from the system in the current stage of the project.

Clinician requirements

For the pilot study, clinicians needed to use the system to report severity scoring of any skin symptoms. They will view photographs of skin symptoms using a separate system, and select the severity of symptoms in this system using drop-down menus within this application.

Research study staff requirements

Research study staff should be able to carry out activities such as adding and managing participant accounts, and viewing participants responses in the system.

During the pilot stage of the study, the participants are asked to obtain food samples, and upload photographs of packaging where possible. Based on this information, the LanguaL [17] food thesaurus will be used by researchers to describe the food(s) identified by the participant, using relevant faceted classifications. After describing the food(s) with the LanguaL food product indexer [17], the classifications can be exported as XML and the system should allow these to be imported, with the data linked to the reported incident.

The system should allow email notifications to be sent to research staff to assist in organizing the study. These should include: notifying them of participants starting/finishing reporting an allergic reaction; uploading photographs; availability of food samples, LanguaL™ food descriptions being attached to an incident; and clinicians inputting severity scoring based on photos of skin symptoms.

Lead research staff requirements

The requirements of the lead research staff summarize the high level goals for the study using the system.

Properties

Realizing challenging requirements

Here we discuss the realization of requirements into properties of the system.

Recruitment and informed consent

The system allows participants to be allocated to a centre (UK or Ireland for the validation and pilot studies) and will automatically generate their study ID. The system presents an online consent form to participants recruited remotely and not in person through attendance at a clinic.

Workflows

When participants log in for the first time, if they are recruited remotely they are presented with the online informed consent form. The data captured by the system is divided into an enrollment questionnaire and an incident questionnaire. The enrollment questionnaire is done once (gender, age, diagnosed food allergy and asthma diagnosis). The incident questionnaire is completed each time the participant reports a suspected allergic reaction. Once the participant has answered the first question of the incident questionnaire, they can upload photos using the *My reactions* page, which lists the completed/uncompleted allergic reaction reports, with dates.

Once the incident questionnaire is completed, the research study staff can use the system to allocate a food sample to be analysed (if one is available). The LanguaL™ food descriptions and symptom severity scores can be uploaded at this point. The system has a list of incidents, and for each incident the status of questionnaire completion and upload of food descriptions and severity scores can be seen.

Photographs

Participants are requested to upload photos, including foods, packaging, and skin symptoms. The photos of skin symptoms are used by clinicians to carry out a reaction severity scoring. After participants upload the photos they can add descriptive text before confirming the upload. As these photos could be personally identifiable, the system only allows participants to upload the photos, after confirming the photo and providing a description, and displays information that photos have been uploaded but does not allow participants to download or view the photos from within the system. Also, clinicians use a separate secure system to view the photos when they complete the severity scoring.

Customizations for mobile devices and tablets

We made a number of modifications so that participants could access the system using a tablet or mobile device. For example, customizations so that more of the page is available to the question items for tablets. Tablets and mobiles do not have a cursor, so we made changes to the system based on hovering over items so that it would work correctly.

Mobile accessibility/web browser

We considered developing a mobile phone application, however due to resources and the large size of the questionnaire, we decided to develop a web application, with some modifications to enable it to work on mobile devices and tablets. However it requires use of a web browser and a network connection to communicate with the server.

Developing a phone application would have the advantage that participants could complete the questionnaire without a network connection and submit the data once a network connection is found. Participants are reminded not to report reactions until they have fully dealt with their symptoms, and the system is a prototype, so we thought this was an acceptable trade-off. Developing a mobile application would consume more resources as we would have needed to use a number of different technologies to produce software for each operating system. With a web application we only need to develop and support one system.

Participants have a *My reactions* page, listing their reported reaction incidents. Once participants start reporting a reaction and have answered the first question item, an incident is added to this list, and they can click a link to upload photos. If they log into the system from a mobile or tablet device supporting the HTML5 media capture *camera* tag they can upload a photograph directly from their device. As there are at most 42 items, we expect most participants to complete the questionnaire via a web browser at a computer or via a tablet, and use a mobile phone primarily as a camera and not to answer the questionnaire.

Source documentation

There is a requirement from clinical staff to be able to print off source documentation, including online consent forms and report reaction incident questionnaire responses.

As the system does not store any names of participants, when printing the consent form (for remotely recruited participants) the clinician can input the names of the participant, and clinical staff and print a hard copy. The system then records that the consent form has been printed.

Validation study results

There were three separate units of analysis at this stage of validation: 81 items of the prototype evaluated using an ES; ES as a psychometric construct; and the initial questionnaire as a psychometric construct.

Thirty-nine adults from Ireland and UK, diagnosed with food allergy, evaluated the prototype online. Tables 1 and 2 show the demographics of the 39 adults, with Figure 3 showing the age distribution. Fifty-four percent of the adults also had asthma, the most common allergies being peanut and treenut.

Individual items were evaluated positively or very positively by participants (60-70% of positive scores across the ES). Qualitative thematic analyses identified four main topics of concern, however these did not relate to the prototype or any of the items, so this data was not used in the subsequent refinement of the prototype.

Reliability of ES was assessed by Cronbach's Alpha statistic with any figure over 0.7 being regarded as good validity. ES yielded .991 Cronbach's Alpha demonstrating a very good internal reliability.

Acceptance during validation study

Our aim is to develop a system that is used to report reactions, here we assess basic measures of the use of the system: the number of questions answered, approximate time to complete the questionnaire, and the number of users evaluating the system by reporting a reaction. This is linked to what users want/need to be able to report accurately and conveniently.

Sixty-three usernames were allocated for the validation study, 39 questionnaires were successfully completed. For the uncompleted questionnaires, only four people started but failed to complete, the remainder did not start the questionnaire.

We recorded the time the first and last question items were submitted to use the difference to crudely approximate the time taken to complete a response. This assumes that participants complete the questionnaire in one session, without stopping. This measure will not capture the duration correctly if for example they log out of the system and log back in later to resume the questionnaire, or pause completing the questionnaire. We have discounted any reporting times over one hour which we can be reasonably sure involved leaving the questionnaire and returning later. The average time for the remaining completion times was 27.5 minutes (minimum 10, maximum 62 minutes). The time to complete the validation questionnaire is likely to be significantly longer than the pilot study, due to the evaluative scale present for each question item; this scale is not used during the pilot study.

Participants did not need to complete all 81 items due to the conditional nature of some question items, the maximum number of items in a completed response was 42, and minimum 29 items. Tables 1 and 2 show baseline characteristics of the participants.

Table 1– Baseline characteristics during validation study

Gender	Ireland	UK	Total
Male	3	2	5
Female	18	16	24
Total	21	18	

Table 2 — Diagnosed allergies during validation study

Allergy	Participants with allergy	Allergy	Participants with allergy
Peanuts	28%	Milk	7%
Treenuts	24%	Wheat	3%
Seafood	9%	Fruit/veg	13%
Egg	11%	Other	5%

Discussion

We developed a prototype system to enable the reporting of suspected allergic reactions in near-real time, capturing a range of information about the context and nature of the reactions. This system has been successfully used in a validation study with 39 participants from the UK and Ireland using it to report an historical reaction.

Our system has some limitations, for example, as it is accessed via a web browser, we require network connectivity to access the system. Participants are asked to upload photographs if these are available. This can be done either by uploading the photos via a web browser from a computer, or, by logging into the system on a phone/tablet with a web browser, in which case the camera on the device can be used. The results of the pilot study will enable us to see whether participants upload many photos; we did not ask participants to upload photos during the validation study.

The validation data indicated some issues with distribution resulting from the voluntary nature of the recruitment, most notably, the sample was not representative of a wider population with 90% of all participants being female. This gender bias will need to be addressed in the next stages of the validation process.

The study asks participants to deal with their symptoms before reporting a suspected allergic reaction, this will result in a delay between the reaction and reporting the reaction. The amount of time passing before reporting symptoms influences the reported symptoms. Therefore as the system captures the time of reaction as a question, and records the time the questionnaire was submitted, in the analysis we could control for time lag between reaction and report.

In regard to the length of the questionnaire, and the validation process, it is important to note that during validation participants only used the system once. For the pilot study they may report along the full spectrum of severity – this is novel because usually only the severe end of the spectrum is presented in accident and emergency hospital departments. This type of information may be used to inform future integrated dynamic models of 'severity' and behaviours.

The validation and pilot studies have involved recruiting participants through clinics, and anaphylaxis campaign websites, and these populations may not be representative of the general population in terms of engagement with the system.

AlleRiC is currently undergoing further validation in its pilot stage, which involves live-reporting of food-allergic reactions.

This phase runs from October 2014 for a period of 18 months. The recruitment strategy for the UK is the University of Manchester population, the UHSM allergy clinic, and Anaphylaxis campaign, and for Ireland includes University College Cork population (there is no clinical involvement in Ireland), GPs, private allergy clinics, Anaphylaxis Ireland members, and through social media. Both UK and Ireland use online recruitment. The eligibility criterion are: adults aged over 18, capable of giving consent, with a physician diagnosed

food allergy. Participants will use the system to report suspected allergic reactions over this period. The resulting dataset will be analysed quantitatively (aspects of food eaten, treatment etc.). A qualitative analysis will be done on suitable text fragments, e.g., open ended text questions, to investigate participant experiences related to allergic reactions to food.

After the completion and analysis of results of the pilot study, cross cultural validation will be undertaken using a multi lingual version of the system across four distinct geographic regions in Europe.

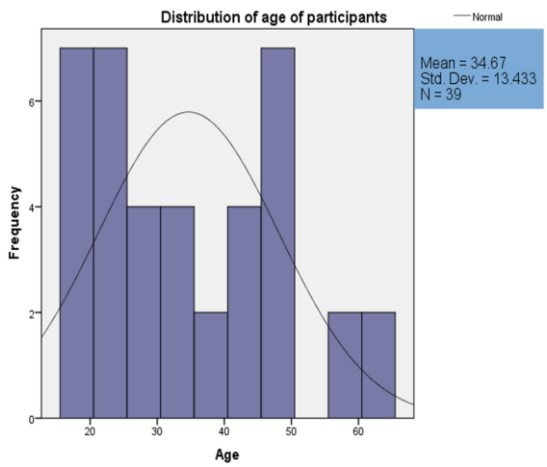

Figure 3 –Age distribution for initial feasibility study

Conclusion

A web based system, AlleRiC has been developed and now enables reporting of suspected allergic reactions to food in near-real time. The system has been used in a validation study with 39 adults from the UK and Ireland who have diagnosed food allergies – successfully reporting historical reactions and evaluating the system. The system is now deployed in a pilot study in the UK and Ireland where participants are reporting reactions prospectively in near real time.

As more people spend more of their lives online there is an epidemiological opportunity to tackle recall bias in ways that might otherwise increase sampling bias due to diferences in technology access. We have used this e-epidemiology tipping-point to address a big gap in food allergy knowledge.

Acknowledgements

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