Application of Analytic Hierarchy Process for User Needs Elicitation: A Preliminary Study on a Device for Auto-injection of Epinephrine

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Abstract. Understanding user needs is essential to design biomedical devices that are efficacious in real life (clinically effective). Few studies propose analytic quantitative methods to elicit user needs. This paper presents a preliminary application of the Analytic Hierarchy Process (AHP) to elicit user needs. As a case study we focused on the use of a biomedical device for auto-injection of epinephrine to treat severe allergic reactions. Although the study presented is on-going, the methods we describe provide valuable insights into how quantitative methods can be applied to user needs elicitation.

Keywords: Analytic Hierarchy Process, anaphylaxis, epinephrine auto-injector, user needs, health technology assessment, medical device design.

1 Introduction

The juxtaposition of economic and clinical evaluation raises new issues in the design of clinical trials. Currently pivotal phase III trials are designed to test safety and efficacy (does the drug work under optimal circumstances?) and not to answer questions about the effectiveness of a drug, which is the more relevant question for health technology assessment (does the drug work in usual care?) [1]. Failure to effectively collect and consider user needs during development has been shown to reduce the real world efficacy (clinical effectiveness) of medical devices, In the literature there are several studies that attempt to address this issue. The majority of these studies use qualitative research methods to investigate why promising health technologies fail in the real world. These studies can provide valuable insights to inform the design of new healthcare services or products; however, often their diffusion among manufactures is limited. One of the reasons is that the results of the majority of these studies are presented as qualitative reports, in a form that designers, and engineers find difficult to appraise and incorporate into the design process [2].

This paper presents an application of a quantitative method to elicit user needs of epinephrine auto-injectors (EAIs) for the treatment of anaphylaxis. In clinical trials these devices have been shown to perform well, reducing mortality, morbidity and

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hospitalization [3]. However, research has also shown that the effectiveness of EAIs is often reduced because patients do not always carry the device with them at all times for reasons other than technical ones [4,5].

The use of sc*ientific quantitative methods to support decision making* is considered necessary in healthcare organizations, where the personnel are committed to follow only the best available evidence according to well-designed trials [6], meta-analyses [7] or network meta-analyses [8]. Nonetheless, despite the hierarchy of evidence, the complexities of medical device decision-making require a spectrum of qualitative and quantitative information [9]. The method proposed in this study to quantify user needs is an adaptation of Analytic Hierarchy Process (AHP) [10], which is a multi-dimensional, multi-level and multifactorial decision-making method already used in medicine [11] and in Health Technology Assessment (HTA) studies [12]. AHP aims to prioritize decisional variables, based on three main ideas: (1) grouping all the variables into meaningful categories and sub-categories, (2) structuring the problem as a decisional tree; (3) performing pairwise comparisons between needs (leafs of the tree from the same node) and needs' categories (tree nodes); defining a coherent framework of quantitative and qualitative knowledge This hierarchical approach allows the construction of a consistent framework for step-by-step decision-making, breaking a complex problem down into a number of smaller, less-complex ones, which decision makers can more easily deal with. This is particularly useful when the decision-makers (in this study, patients) are not familiar with complex decision making methods [13]. At the moment of preparing this paper, both tree and questionnaires are being piloted among researchers experienced in user needs elicitation and with a selected group of EAI users who have already participated in previous user needs assessment. A final version of a 'tree-of-needs' and a corresponding questionnaire is expected to be submitted to a wider number of users in the next three months.

In this paper, after describing the case study, the method is introduced and the preliminary version of the tree-of-needs and questionnaires are presented.

2 Case Study

Anaphylaxis is a life threatening allergic reaction which affects the respiratory and/or cardiovascular systems [14]. A key component in the treatment of anaphylaxis relies on the patient providing routine self-care and management to prevent this occurring [15]. Whilst anaphylaxis may be triggered by exposure to latex rubber, insect venom and medication, the most common cause is exposure to foods including peanuts, nuts, fish, milk and eggs [16]. The incidence of anaphylaxis has risen dramatically in recent years, as reflected by a sevenfold increase in anaphylaxis-related UK hospital admission between 1990/1 and 2003/4 [17]. The treatment of anaphylaxis is a prompt intramuscular injection of epinephrine, typically administered by the patient themselves. It is therefore not surprising that prescriptions of EAIs have risen, with 10,700 prescriptions being issued in England in 2001, rising to 21,100 in 2005 [18]. Patients considered at risk of anaphylaxis are prescribed at least one EAI, which in accordance with self-care best practice for this condition, is to be carried by the

patient at all times so that the device is readily available for rapid self-treatment when necessary [19]. It is widely accepted that not having an EAI available at the scene of a severe anaphylaxis event puts the patient at significant risk of a fatal outcome [5].

Although EAIs have been designed to be used as self-treatment devices by patients there is evidence to suggest that patients often do not engage in appropriate self-care practices such as the carriage and use of the device when necessary [4]. A study of fatal anaphylactic reactions revealed that only 10% of individuals actually had epinephrine to hand when it was required [20], and even when the device is to hand, it is often not used [21].

Despite the serious consequences of not having such a device to hand, there is a lack of research that considers the experiences and attitudes of patients and the strategies they use in the delivery of care for this condition. More specifically, to the best of our knowledge, little research has been carried out to specifically explore, from the adult patients' perspective, what patient motivations are for carriage or non-carriage of EAIs and/or their deployment/non-deployment at appropriate times [22].

3 Method

The following nine steps describe the whole method of this study, although at this moment the steps 4-9 are not yet completed:

1. User needs identification. This step directly involved 2 domain experts (JB and AM) and fifteen device users (interviewed in a previous study).
2. Design of a tree-of-needs with nodes (categories), sub-nodes (sub-categories) and leaf (needs). This involved 1 expert of user needs elicitation (JM) and one researcher experienced in the AHP (LP).
3. Development of questionnaires (1 AHP expert).
4. Tree piloting. This involves "n" domain expert/s, where n is dynamically established according to variability among experts' opinions.
5. Questionnaire piloting. This involves a small group of selected responders (from 3 to 5), with experience of participation in user needs elicitation studies.
6. Final tree and questionnaire development (1 AHP expert, 1 domain expert and 1 experienced elicitor).
7. Final questionnaire submission.
8. Data analysis end results presentation (1 expert of AHP)
9. Results interpretation and discussion (1 expert of AHP, domain expert, 1 elicitor and some users).

The AHP method is applied following the workflow represented in the Figure 1. Details about AHP methods can be found in other papers [23-25], which are freely accessible (`http://eprints.nottingham.ac.uk/`). We do not describe the method in detail as no further modification was proposed in this study. In the following sections we describe the methodological details that are relevant to this study.

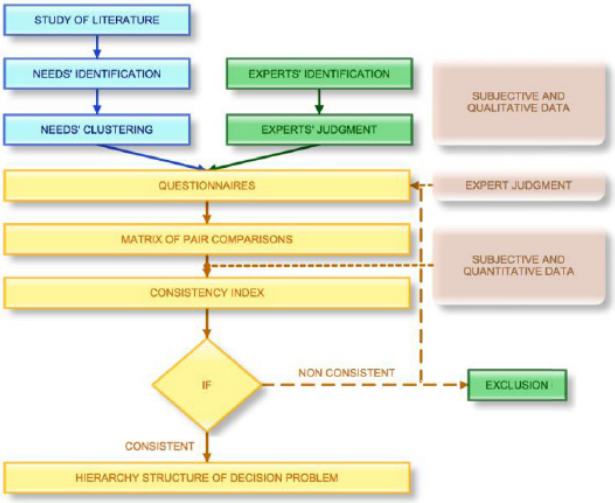

Fig. 1. AHP Method

3.1 Questionnaires Design

The questionnaire was designed to minimize possible responder bias. For instance, each element was presented the same number of times on the top left and the right, at the top and at the bottom of the questionnaire as responders writing from left to right and top-down can be more likely to judge the elements on top-left as more important than those bottom right. Moreover, the sequence of comparisons (A with B, B with C and C with A) was adapted to minimize intransitive judgments and no more than 4 elements were included into each category, to ensure the number of questions included in each questionnaire was not overwhelming for the user. Finally just 5 levels of the Saaty scale were used in order to facilitate responder consistency. The questionnaire was first piloted in the lab and then with a small group of patients, who had already participated in previous studies.

ACCORDING TO YOUR PERSONAL EXPERIENCE, HOW IMPORTANT IS EACH FACTOR ON THE LEFT COMPARED WITH EACH ONE ON THE RIGHT IN CHOOSING NOT TO CARRY THE EPIPEN? REGARDING THE "**SOCIAL ISSUES**", AND ESPECIALLY "**OTHER PEOPLE OPINION**", IN YOUR EXPERIENCE:

HOW PEOPLE PERCEIVE YOU	IS	*MUCH MORE*	*MORE*	*EQUALLY*	*LESS*	*MUCH LESS*	IMPORTANT THAN	***HOW PEOPLE PERCEIVE THE EPIPEN***
HOW PEOPLE PERCEIVE THE EPIPEN	IS	*MUCH MORE*	*MORE*	*EQUALLY*	*LESS*	*MUCH LESS*	IMPORTANT THAN	***HOW PEOPLE PERCEIVE YOUR CONDITION***
HOW PEOPLE PERCEIVE YOUR CONDITION	IS	*MUCH MORE*	*MORE*	*EQUALLY*	*LESS*	*MUCH LESS*	IMPORTANT THAN	***HOW PEOPLE PERCEIVE YOU***

Fig. 2. Example of questionnaire

4 Results

The preliminary tree-of needs that was developed as a result of carrying out this process is presented in Figure 2.This tree was used to develop the questionnaire according to the layout presented in Figure 3.

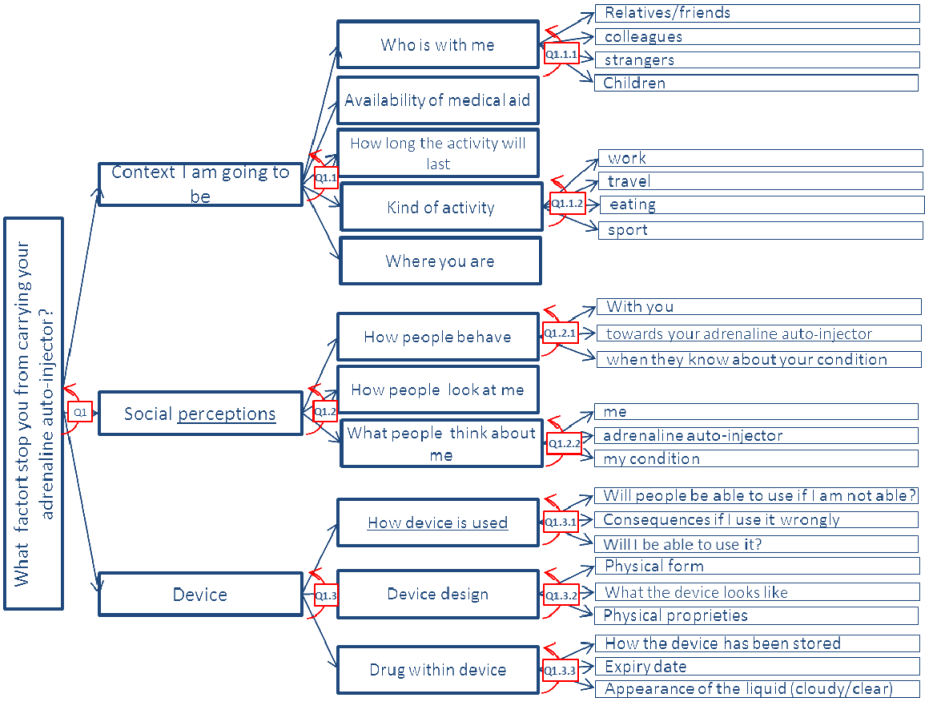

Fig. 3. Needs tree hierarchy design

The hierarchy and the questionnaire are currently undergoing piloting among other researchers and a selected group of patients who have already participated in previous user needs assessment. The final version of the questionnaire is expected to be completed and analyzed in the next three months. Nonetheless, the process of creating the hierarchy illustrates how qualitative data can be used as a basis for a quantitative investigation into user needs. The next steps of this study will also provide qualitative information about the relative importance of each need compared to all the others. This will allows experts, and especially manufacturers, to focus on those needs that users considered more important.

5 Conclusion

In this paper, an application of the AHP to elicit user needs was presented. This is an important issue in HTA as the user needs that affect the efficacy of biomedical

devices in the real word (effectiveness) are often underestimated. Although a growing sensitivity to these issues has recently been demonstrated, few studies have proposed analytic methods to investigate them. The preliminary results presented here (mainly the tree-of-needs) have already provided a useful and interesting way of analyzing, synthesizing and transforming user data which were collected during previous qualitative studies. This paper demonstrates how AHP can be used to transform user data into a form that can be more easily incorporated into medical device design. It is hoped that this method will provide a means of bridging the gap that has been shown to exist between the broad and rich nature of user research and the specific and focused requirements of manufacturers when using this data to produce design specifications. Finally, qualitative information about the priorities of needs will complement the quantitative insight.

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