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Project:

MyAirCoach - Analysis, modelling and sensing of both physiological and environmental factors for the customised and predictive self-management of Asthma"

(MyAirCoach, Grant Agreement No. 643607)

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D1.2 User requirements, use cases, UCD methodology and final protocols for evaluation studies

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Executive Summary

The current deliverable is directly connected with the work performed under the Tasks T1.2 “User Requirements, clinical procedures and MyAirCoach use cases” and T1.3 “MyAirCoach User Centred Design methodology” and serves as a detailed summary of their outcomes towards the project objectives.

The requirements and outcome specified here are based on several inputs: a) the MyAirCoach Description of Work (DoW) document, b) the current advances in the state-of-the art in the research and technology fields described by the MyAirCoach project within the T1.1 “Analysis of current practices” (deliverable D1.1), c) the outcome from the plenary project meetings, d) the input from several informal discussions among the project consortium, and finally e) the opinions and expectations of MyAirCoach end users through focus groups sessions and surveys.

The main goals of this deliverable are:

- The specification of the outcomes expected by the project;
- The identification of target user groups;
- The detailed specification of the user requirements ;
- The definition of the MyAirCoach reference Use Cases and scenarios;
- The definition of the User Centred Design Methodology ;
- The definition of the evaluation protocols for the evaluation studies;
- The incorporation of market research in the projects methodology

Therefore this deliverable focuses on the MyAirCoach system components and outlines the related requirements and specifications needed to optimally address the proposed functionalities of the final product and to establish strong and valuable connections with the actual needs of the targeted user groups.

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List of abbreviations and acronyms

(*in alphabetic order*)

APF	Advisory Patient Forum
DoA	Description of Action
DoW	Description of Work
HCP	Healthcare professional
KPI	Key Performance Indicators
NHS	National Health Service (UK)
R&D	Research and Development
REC	Research Ethics Committee
SME	Small and medium enterprises
UCD	User Centred Design
UCS	Use Case Scenarios
UML	Unified Modelling Language
WP	Work package

1 Introduction

This deliverable describes the MyAirCoach User requirements, use cases, UCD methodology and protocols of the evaluation studies as they were defined within WP1. The purpose of the deliverable is twofold: a) to identify the requirements of the key users (patients, healthcare professionals, and researchers and related SMEs) and b) to define the methodology for the design of the MyAirCoach system so that it fully addresses these users' needs.

The report begins (Chapter 2) with a short description of the project in regards to the objectives of the first work package in order to underline the positioning of the current deliverable in the workplan of the MyAirCoach system. In detail, and after a short introduction to the difficulties that are faced by asthma patients and healthcare professionals and the importance of self-management approaches, the main objectives of the MyAirCoach are presented in relation to the outlined need for accurate assessment of user requirements and their use throughout the design and development processes of the myAirCoach system.

The next part of the document (Chapter 3) focusses on the collection of user requirements, the interpretation of which will form the basis for the design and development of the MyAirCoach system in the future stages (M13 to M36). More specifically, the scheduling and the design of appropriate assessment campaigns is presented among the involved focus groups and surveys that include asthma patients and health care professionals. The following analysis and interpretation of the collected data serves as the connection of the project objectives with the actual needs of the various users and provides a very important starting point for the User Centred Design process that will be followed throughout the timeline of the project.

The next section of the document (Chapter 4) includes a detailed definition of the Use Case Scenarios (UCS) which will be used in the evaluation process of the integrated system in the final stages of MyAirCoach. A detailed table is provided for every scenario presenting its most important characteristics and parameters in addition to a detailed UML diagram. More specifically, three categories of use cases are separated, depending on the main user group that they involve. Firstly, the category of User Oriented UCSs includes the scenarios that involve exclusively patients without the direct input or interaction by healthcare professionals. The second category of UCSs is oriented to the support of healthcare professionals so as to increase the efficiency and effectiveness in regards to asthma management. The use cases that include functionalities that support researchers for the understanding of asthma disease are grouped in the third and final category of UCSs.

The following sections of the deliverable (Chapters 5, 6 and 8) are aiming to form the fundamental basis upon which the User Centred Design (UCD) methodology of MyAirCoach will be formed in the course of the project. In Chapter 5 a detailed review of the available methodologies is presented together with their relevance to the project objectives and specific work packages or tasks. More specifically, the next sections outlines the specific UCD methodology of the MyAirCoach project (Chapter 6) and the incorporation of a product life-cycle approach that is aiming to stimulate the commercialisation of some of the project's outcomes and transform the collected user feedback into valuable conclusions to be used in the related market analysis.

2 Problem Definition: Optimising the methodology of asthma assessment, treatment and self-management

2.1 Asthma Disease

Epidemiology and Magnitude of Asthma's Disease

Asthma is a major chronic disease of the airways that affects more than 235 million people worldwide[1]. In Europe, 30 million adults suffer from asthma[2], while the number of children suffering from the disease is continuously rising in eastern countries towards the high levels of prevalence observed in the western part of Europe[3]. This diversity of asthma prevalence is a global rather than a European phenomenon[4] and reveals the inability of even developed countries to effectively support asthma patients[5],[6]. All the above, together with the wide spectrum of socioeconomic consequences of asthma disease that reduce the quality of life of patients and the efficiency of the healthcare system[7], underline the need for novel healthcare approaches and innovative devices that can support patients and healthcare professionals.

Etiology and Risk Factors

Asthma is a complex disease that can be aggravated by various personal health behaviours as well as environmental triggers. Risk factors for either the development of asthma or triggers of asthma exacerbations include viral and bacterial infections[8], environmental exposures such as aeroallergens[9], pollution[10], tobacco smoke[11], lifestyle factors such as living on a farm[12], diet[13], and antibiotic use[14], and co-morbidities including atopic dermatitis and obesity[15]. Studies have shown that these factors can result in increased asthma episodes or exacerbations, increased asthma severity, decreased asthma control, and increased utilisation of health care services. Disease severity (hospitalisations, frequency and severity of exacerbations, and loss of lung function) also contributes as a risk factor forming a vicious cycle of declining health that is very difficult to break and usually leads to severe and life threatening asthma attacks.

2.2 Asthma Self-Management

According to national and international guidelines the aim of asthma treatment is to achieve and maintain asthma control, including symptoms, sleep awakenings, increased use of reliever medication, and activity limitation for prolonged periods of time[16,17]. However, in reality long-term asthma management falls short of the goals set in international guidelines and asthma control is found to be sub-optimal in the vast majority of cases[18]. Daily monitoring of symptoms and signs may subsequently prevent exacerbations by simply allowing patients to increase their medication dosage when the risk of exacerbation is calculated above a predefined threshold[19]. Furthermore, self-management approaches such as weekly control monitoring, instant treatment advice and an action plan in combination with online- and group education and communication with a healthcare professional has been demonstrated to provide a sustained improvement in asthma-related quality of life, asthma control, lung function and the number of symptom-free days as compared to usual care[20,21]. It is therefore evident how self-management of the disease by patients themselves is an important aspect in improving their quality of life.

Increasing the efficiency of the healthcare system

It is widely accepted that in the current healthcare environment, user involvement could be beneficial for both the health of individual patients and the cost effectiveness of the health system as a whole. The observed increase in the prevalence of chronic respiratory diseases in combination with the resulting escalation of related costs, further underlines this need and is a driver for research in this area. Asthma, as a major factor of this equation, is found to be positively influenced by self-care support interventions[22] especially when supported by electronic media[23,24]. In addition to the beneficial effects on health treatments[25,26] and patient behaviours',[27], digital self-care interventions are found to reduce the symptoms of asthma, improve lung function and lead to lower clinical appointment return times and fewer hospitalisations.

Asthma mobile health

Modern smart devices are expected to play a major role for the adoption of novel healthcare models since they offer a platform upon which software and hardware solutions can be implemented. Recent publications introduced novel approaches for analysing breathing audio signals[28] and took the first step towards the integration of asthma monitoring devices and smartphones[29] [30] [31]. Furthermore, smartphone applications are continuously being developed in order to help healthcare professionals and patients, supporting their communication and addressing critical healthcare issues[32] [33]. A critical component of communication addressed by both research[34] and commercial devices[35] is the interaction between patients of younger age and their families. Social interactions and communication between asthma patients is another fundamental model supported both by research[36] and a commercially available technology[37].

2.3 Importance of User Involvement for MyAirCoach objectives

Based on the above description of asthma and the evident importance of patient involvement in all stages of managing the disease, the MyAirCoach project was planned to be centred on the needs and requirements of patients. In this way, and through the formation of user feedback mechanisms, the MyAirCoach project will be used to optimise the usefulness and usability of all developed components in order to increase the final impact of the system with regard to quality of life of patients. The following Table underlines the importance of defining and understanding users' requirements for the main objectives of the project.

Table 1: Importance of user involvement in the MyAirCoach objectives

MyAirCoach Objective	**Importance of user involvement**
Objective 1: *Continuous, context-aware, multi-parametric monitoring of asthma related parameters, activity, lifestyle, and environment*	Create a smart monitoring framework that can comply with the needs and requirements of the patients for increased privacy whilst providing researchers and health care professionals (HCPs) with adequate information (measurements, data, models) so as to a) better understand their patient's asthma and b) assist their patients in a personalised manner.
Objective 2: *To Design and integrate miniaturised sensors into a novel small and lightweight inhaler prototype device*	*Develop an easy to use smart inhaler device that should be acceptable to the patients and that does not introduce any risks to their privacy and safety.*
Objective 3: *To develop a "personalised monitoring and guidance mHealth platform"*	Develop a personalised system that can assist patients to manage their asthma through intuitive and easy to use interfaces that will increase their adherence to their prescribed medication.
Objective 4: *To develop a patient-specific physiological and environment-aware computational model for asthma disease*	Develop patient specific computational models that can be used by the scientific and medical community in order to understand their patient's asthma .
Objective 5: *Test campaigns with beneficiaries*	Involvement of patients and health care professionals in relevant test campaigns and in compliance with all the relevant ethical requirements.
Objective 6: *Exploration of the predictive value of new physiological markers that may enhance predictability of asthma*	Safeguard the privacy of patients and develop anonymised datasets that hold significant informational content to allow the extraction of useful results.
Objective 7: *To validate the resulting MyAirCoach project system in real-life scenarios*	The definition of use case scenarios will be based on important user requirements, and thus will be highly connected with the actual

	needs of user groups.

More specifically, the ambition of MyAirCoach is to utilise state-of-the art technology integrated with a smart sensing infrastructure and clinical prediction models in order to provide personalised feedback to patients on how to manage their condition in their home or at work, without the need to have frequent face-to-face contact with healthcare professionals in the hospital or clinic. In this way, the final MyAirCoach system will need to be intuitive and easy to use by patients of different ages and educational backgrounds and also address the needs of **patients** to further increase their involvement in the healthcare process. Ultimately, the ambition for MyAirCoach is to be a personalised sophisticated, unobtrusive, cost efficient and lightweight health self-management system that can empower and give confidence to patients to manage their asthma so as to improve their day-to-day quality of life.

MyAirCoach will also allow **healthcare professionals** to have a detailed and accurate picture of the patient's health state when they are away from the clinic environment and allow an objective assessment of the patient's current level of asthma control in order to determine the best treatment strategy. Healthcare professionals will also be able to estimate disease evolution based on the patient's physiological and environmental monitoring. It is therefore very important to outline the needs and requirements of healthcare professionals and develop all the software tools that will allow them to support their patients more effectively and through a more efficient manner.

3 MyAirCoach User Requirements and Goals

This section focuses on the identification and analysis of the MyAirCoach user requirements and needs.

3.1 User Requirement Assessment and Goal Identification Methodology

The methodology of identifying the user needs and requirements can be divided into the following phases, as illustrated in Figure 1:

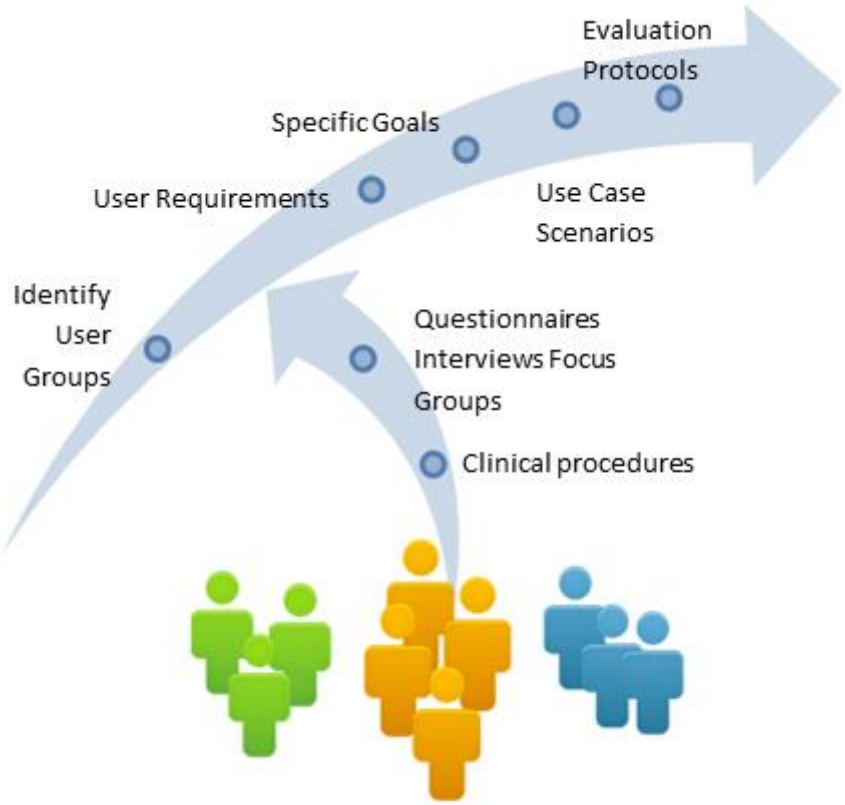


Figure 1: The phases of the identification of the MyAirCoach User Requirements

Initially, stakeholder groups who will utilise the system need to be identified, along with the clinical procedures that are currently undertaken in the management of asthma. The most important user groups can then be questioned to establish and understand their needs and requirements of a mobile health system that can assist in the personalised management of asthma. This information should be obtained using multiple methods to ensure its robustness. An understanding of each user group's requirements will allow the goals of the system to be fully defined and appropriate use case scenarios for each of the supported user groups to be implemented. The definition of the use case scenarios will then form the basis of the evaluations protocols within WP6 of the project.

3.2 MyAirCoach Target User Groups

The Target User Groups that will make use of and benefit from the MyAirCoach models and tools can be divided in two main categories:

- ***Medical healthcare professionals.*** This group of users directly treat people with asthma and therefore have an insight into what would be beneficial to their patients. The term health care professionals (HCPs) includes clinicians, respiratory nurses, clinical physiologists, physiotherapists and other medical professionals within asthma care. MyAirCoach aims to provide HCPs with a more detailed and accurate description of a patient's asthma state and therefore more improved and accurate decision support as to when and how a particular patient should change their treatment and have an appropriate intervention. It will also allow them to monitor their patients' progress.

- ***Patients*** The needs of asthma patients and their surrounding social environment must be at the centre of the MyAirCoach project. Determining the opinions and needs of people with asthma on the functionality of mHealth is the first step in designing the next generation of 'user-centred' mHealth products. Patients will be involved in all the phases of this project starting from the definition of the requirements, as discussed in section 3.4, up to the validation and the assessment of the benefits of the proposed solutions (WP6).

  The myAirCoach tools aim to enable patients to have an overall view of their health status and lifestyle and assist them to evaluate the overall benefits of specific personalised interventions and relevant lifestyle management. It should also enable patients to have a more personalised view of their treatment (e.g. the types of medication taken and individual asthma action plans) based on the monitoring of several clinical, behavioural and environmental measurements. Finally, it should enable patients to modify their treatment towards personalised pre-set goals and guidelines (e.g. health lifestyle, dietary habits etc.), either automatically or driven by the patient themselves or a healthcare professional.

3.3 Research governance

All clinical procedures that may be required in the assessment of user requirements and the User Centred Design processes should always comply with the maximum requirements for the protection of privacy, data security, safety. In addition all procedures should be in agreement with the projects Ethics Manual as it will be outlined in D8.3 *Ethics, safety and mHealth Barrier issues (regulation, legislation, etc.).*

The following sections describe a programme of research to determine the opinions of individuals with asthma and of healthcare professionals on the use of mHealth systems to support asthma self-management. In short, patients and healthcare professionals in the UK and the Netherlands were invited to participate in focus groups and to complete surveys (further details of the research are presented in sections 3.4 and 3.5).

3.3.1 Ethics

To protect the rights, safety and wellbeing of research participants, all UK based medical research must receive ethical approval by a NHS Research Ethics Committee (REC). Similar regulations and ethical approvals are required in the Netherlands. The ethics committee reviews applications for research and ensures that the requirements placed upon the participants are acceptable. It also reviews all study documentation (e.g. patient information sheets, consent forms, topic guides etc.) to ensure that participants receive sufficient information to help them decide whether they wish to participate in the research. Following ethical approval, research conducted in NHS organisations must also obtain management permission (R&D approval), from the NHS organisations responsible for hosting the research.

This research underwent ethical review and was given favourable opinion by research ethics committees in the UK and the Netherlands. In the UK, the NHS National Research Ethics Committee, East Midlands (Derby), reviewed the application and provided ethical approval. In the Netherlands, ethical approval was provided by the Ethics Committee of the Leiden University Medical Center. The University Hospital of South Manchester NHS Trust provided R&D approval as the host organisation. The ethics and R&D approval documentation are provided in Appendix 1: Ethics application and approval documents.

3.3.2 Data Protection

All data collected for this research was handled in accordance with the Data Protection Act 1998 and the NHS Code of Confidentiality. These are policies that must be observed by all who work within NHS England and have access to person-identifiable or confidential information. Indeed, all NHS employees are bound by a legal duty of confidence to protect personal information that they may come into contact with during the course of their work. This is not just a requirement of their contractual responsibilities but also a requirement within the common law duty of confidence and the Data Protection Act 1998.

Data collected during this research were handled with appropriate care. Specifically, the video-recordings were made on encrypted video recording devices and transferred to encrypted computers. Transfer of data between devices was done using encrypted

storage devices only. Following transcription, the video recording was removed using appropriate data destruction software. Paper copies of consent forms, clinical research files and paper surveys were stored securely in a locked cabinet at the associated host institutions. During the transcription process, personal identifiable information was removed, ensuring that any reports protect the anonymity of the study participants. Participants provided written informed consent for their data (incl. direct quotes), in an anonymised format, to be shared with other researchers and published as part of this research.

3.3.3 Advisory Patient Forum

In addition, EFA and Asthma UK have assembled a dedication Advisory Patient Forum (APF) for the duration of the project. They will provide continuous feedback from patient experts, assure inclusion of the patients' perspective across all project Work Packages, and ensure the disease management models will address users' specific and will be understood for the lay target group. Specifically, the APF have assisted in the formulation of topic guides for the focus groups and subsequent surveys to gain user-requirements

3.4 Design of the Requirements' Assessment Campaign

Mobile Health (mHealth) provides new opportunities to assist asthma self-management practices. As indicated in the DoW, It has been proposed that a user-centred design approach during the design and development of mHealth systems may allow for the technology to meet the users' expectations and ultimately improve user health outcomes. Determining the opinions of individuals with asthma and of healthcare professionals on the functionality of mHealth is the first step in designing the next generation of 'user-centred' mHealth products.

In this direction, we conducted a specific programme of research to determine the opinions and needs of individuals with asthma and of healthcare professionals on the use of mHealth systems to support asthma self-management and personalised treatment. This research constitutes the first step in designing a user-centred mHealth system for asthma self-management.

Two methods were applied sequentially to establish user requirements: firstly focus groups were conducted with individuals with asthma and with healthcare professionals. Secondly, surveys were completed by individuals with asthma and healthcare professionals to quantify some of the opinions generated during the focus groups as described with details in the following paragraphs.

3.4.1 Stage one: Initiation

The first stage of the process focussed on the identification of potential partner organisations which can provide access to a wide range of participants. Anyone living in the UK or the Netherlands with experience and understanding of living with asthma was considered eligible to participate in the identification of uncertainties and their prioritisation.

Partners identified were Asthma UK and EFA, who are patient organisations which offer support to people with asthma; and University of Manchester, Imperial College London and Leiden University Medical Centre who are all associated specialist asthma centres.

3.4.2 Stage two: Development on methodology

The methodology to establish user needs was proposed by Asthma UK in consultation with senior clinical researchers at the University Hospital of South Manchester, the Royal Brompton Hospital and Leiden University Medical Centre (Netherlands). A combination of qualitative and quantitative methods was proposed, to allow triangulation and ensure that the findings were rich, robust and comprehensive. Focus groups with the two main user groups serve to identify issues of importance and provide understanding and context around these issues as well as the range of divergent opinions within the stakeholder group. Focus groups are usually conducted until saturation of themes is established. Following the identification of issues of importance, surveys of the two user groups allowed a much larger sample of each stakeholder group to express an opinion, and for the collection of quantitative data which will help establish and prioritise the specific needs that the MyAirCoach system should address.

The patient advisory forum, set up by the myAirCoach project (http://www.myaircoach.eu/), were also involved in developing the research protocol. Furthermore, the professional advice from a qualitative researcher, Prof Ann Caress, School of Nursing Midwifery and Social Work, University of Manchester, was sought. This study has received favourable opinion from these partners.

3.4.3 Stage three: Focus Groups: Topic Guide development and Recruitment

The focus groups were designed to use a semi-structured funnel style of questioning (broad to specific). This type of questioning makes it possible to identify the participants' general perspectives in the early part of each discussion, before they are influenced by more specific aspects presented to them later in the session. Topic guides with themes for questioning and prompts to probe for further details if necessary were developed by the partners and were refined following discussion with the APF. These themes included: measurement taking, burden of automated and inputted data, alerts and reminders, user feedback, user support, privacy, product design and other additional functions. The final topic guides are shown in Appendices 2-3.

Outpatients from asthma clinics at Wythenshawe Hospital and the Royal Brompton hospital were recruited by the team at the University of Manchester. Outpatients from asthma clinics at Leiden University Medical Center were recruited by the team at Leiden University. They were provided with details of the research. Patients were also recruited using Asthma UK's website and social media pages. Healthcare professionals were recruited from the asthma clinics and Wythenshawe Hospital. Sample size and composition was determined pragmatically based on the three research centres (Manchester University, Leiden University and Asthma UK).

Participants who responded to the study advert were contacted by the research team to determine their eligibility and were provided with detailed information about the research. In the case that additional participants (more than 8 per centre) expressed an interest in participating, they were selected at random ensuring at least half the patients had severe asthma (if possible). This decision was made as individuals with severe asthma are more likely to use or have used mHealth devices. To allow for participants to be grouped into different asthma severities, they were asked to complete the asthma control survey (a commonly used, validated survey to determine current asthma control/severity) over the phone during enrolment.

3.4.4 Stage four: Focus groups: Data collection and Analysis

Four focus groups were planned; three with individuals that have asthma (patient focus groups) and one with HCPs. The patient focus groups were held in 2 locations in the UK, Wythenshawe Hospital, Manchester and at Asthma UK's Office, London and in Leiden (Netherlands) by Leiden University Medical Centre. The focus group with HCPs was held at Wythenshawe Hospital, Manchester.

Each focus group first determined participants' knowledge of current mHealth devices. This was followed by a short presentation which described the functions of existing and

future mHealth and home monitoring devices, and introduced the topics for the remaining discussion. The presentation was entirely factual and did not contain opinions or data which may have biased the answers.

Each focus group was video recorded and subsequently transcribed. Descriptive framework analysis was applied to the transcripts[38] to allow for analysis within and across the different participants. This was particularly useful to compare the views of patients to those of healthcare professionals. The results of this analysis informed the surveys which were subsequently developed and sent out to people with asthma and healthcare professionals.

3.4.5 Stage five: Surveys: Survey development and Recruitment

Questions were developed to address the themes that were discussed in the focus groups and were refined following the thematic analysis of the focus group data. There were questions relating to participants' knowledge of mHealth products for asthma management, measurements, alerts and reminders, user-feedback, user-support, privacy, product design and any other additional features. Both surveys were designed to take a maximum of 5-10 minutes to complete to ensure a high retention rate, and the question format was largely multiple choice to enable this. The final versions of the surveys for all the involved stakeholders are summarised in Appendix 4: Patient Survey and Appendix 5: HCP Survey.

An advert inviting participants and healthcare professionals to complete the survey online was distributed in December by patient organisation groups including Asthma UK, the European Federation of Allergy and Airways Diseases Patients' Associations (EFA) and by the clinical teams at Wythenshawe Hospital and the Royal Brompton Hospital. The advert outlined the eligibility criteria to take part.

The first page of the survey provided information about the research and outlined the participants' rights. By clicking through to the first question on the survey having read the information for participants, it was assumed that participants had given informed consent to participate. The aim was to achieve approximately 200 responses in total; 150 patient responses and 50 healthcare professional responses.

3.4.6 Stage six: Surveys: Analysis

Predominantly quantitative data was generated from the surveys and this is described in section 3.5.2. Differences between asthma severities, user groups (patients vs healthcare professionals) and other relevant demographic analysis was conducted using parametric and non-parametric difference tests as appropriate. A small amount of qualitative data was generated and this was subjected to thematic analysis.

3.5 Assessment and Analysis of MyAirCoach User Requirements

Ensuring that the MyAirCoach project is effective in addressing the needs of target users, is of crucial importance, especially when viewed as a problem with significant and important socio-economical parameters and dependencies. The detailed results of the focus groups and surveys will be presented separately for people with asthma and healthcare professionals in order to outline the differences that may stem from these two main user groups. Finally a synthesis of the results will allow the overall understanding of the results at a holistic level.

3.5.1 Findings from focus groups

Focus group participants were recruited for each of the four sessions and their demographics are shown in table 2.

Table 2Template for the analysis of the MyAirCoach system through high-level use cases

Location	Number of participants	Gender	Average age	Asthma severity
London	7	4 Female, 3 Male	26.7	2 had a severe exacerbation in the last year; remaining 5 were mild-moderate
Manchester	4	4 Female	31	In the last year, 1 had 13 exacerbations and the others had between 2 and 4 exacerbations
Leiden	8	6 Female 2 Male	29.2	1 had 2 severe exacerbations in the last year, remaining 7 were mild-moderate
Manchester (HCP)	5	3 Female, 2 Male		All treat all types of asthma: 2 asthma clinicians, 2 asthma nurses, 1 respiratory physiologist

The presentation slides given at each focus group can be found in Appendix 6.

3.5.1.1 Patients

Existing knowledge of mHealth and asthma, and any experiences or expectations of using it

Patients in all three focus groups had an awareness of mobile health applications for general health, e.g. fitness/exercise tracking and diet/nutrition, and there was varying usage of these types of applications (apps) among the participants. The majority were not aware of asthma-specific apps and very few had ever used an asthma app.

In terms of expectations, participants expressed a range of suggested uses/benefits of mHealth including:

- Reminders to take preventative inhalers
- Awareness of how much reliever inhaler had been taken
- A way to record symptoms over several weeks and be able to show these to a HCP
- Some milder patients were frustrated by the annual asthma check-up when they felt they were well controlled; perhaps mHealth could evidence that they are well controlled and therefore don't have to attend an asthma check-up when they are well
- Provide a trustworthy source of information about asthma so that an appointment with a HCP is not required

Measurements that might help control asthma or prevent asthma attacks

Participants thought that heart rate would be useful, although a system would need to know when a patient had just taken their inhaler or other medications which alter heart rate. They also thought that night-time breathing/wheezing would be useful; one person had used a Fitbit to look at this but it could not distinguish between night-time movement and respiratory-specific effects. The group acknowledged that peak flow was useful but the current method of using it and plotting results onto a graph is too much and they perceive little benefit unless they were feeling unwell. There was less enthusiasm for allergen sensing (pollen, dust, pollution) and several participants felt that ensuring that they had their inhaler with them would probably be more useful because avoidance of allergens wasn't always possible, or desirable (e.g. cold aisle in supermarket, visiting friends who have pets, exercising). Cough counting received mixed views; some participants said they would find this very useful, others not at all.

Burden of automated data

Participants were happy for things to be monitored automatically, but they did not want to wear lots of different devices. Also, there was concern that additional functions/sensors on a phone would mean the battery life was reduced. Participants were particularly clear that it was vital to tailor what was measured to the individual. The issue of how many devices will need to be carried, and what size they were generated a lot of discussion, with the consensus opinion that integrating everything onto one device that is already carried would be the best solution. Wearable technologies are still a matter of taste/style as to whether someone will choose to wear it, and when. There was also reluctance to incur cost of additional devices at a personal level, and it was unclear whether the health system will pay for this. In terms of specific examples of automated data collection, there were mixed opinions on monitoring activity levels, and mild-moderates were not enthusiastic about having a sticking plaster to record respiratory sounds, particularly if it was large and/or visible.

Burden of lung function measurements

For those with well controlled asthma, lung function testing in the home was acceptable but they would be unlikely to do it on a daily basis; weekly was felt to be more realistic. When not controlled they would be more likely to do this daily. There was a suggestion that linking this testing with gaming features may increase propensity to complete the testing more frequently.

Burden of inputting data

Participants were very clear that they would not measure a whole list of things; perhaps one or two that were relevant to themselves, and they would ignore alerts for anything else. There was also a feeling that some patients, perhaps those with more well-controlled asthma would not be motivated to input data on a long term basis, i.e. once the novelty of the system wore off. In terms of surveys, participants felt they would be unwilling to complete these more than once or twice a year, unless they felt the questions were particularly relevant.

Alerts and reminders

The following alerts and reminders were suggested as being potentially useful:

- Provide an alert when the reliever inhaler was being used too much. One group discussed this and did not have a consensus agreement on what 'too much' use was, therefore there could be a role for education
- The asthma action plan could be stored on a patient's phone
- The patients' phone beeps if they leave the house without their inhaler
- Reminders to take antihistamines in advance of exposure to allergens (if planned)
- An alert to clean the inhaler
- An alert to take their preventer inhaler
- An alert that the preventer inhaler is running out. Whether it would be possible to link this to a repeat prescription
- Feedback on the inhaler device to show whether their inhaler technique was correct

One group discussed the possibility of a smart alert, given that daily schedules could be quite variable. This alert would be sent when the system sensed they had got up, and could not be ignored; the only way to turn it off would be to take the inhaler. Similarly, one participant quoted that they got hundreds of alerts on their phone every day and this alert would need to be different in order to stand out.

Recommendations and User Feedback

In terms of the likelihood of following recommendations, participants would be influenced by who was supplying the system (healthcare providers or the pharmaceutical industry), and whether the recommendations correlated with their existing knowledge of the condition. Most said they would presume the recommendations were trustworthy and would at least trial the system. Most

participants also felt that if the system providing reasons or data to support the recommendation, it would increase their likelihood of following the recommendation.

User support

Participants felt that access to a doctor online would be useful, as long as that doctor had access to the individual person's data and history. There were mixed opinions about forums where people with asthma support each other. On the one hand this could be a useful source of coping strategies and peer to peer support, but on the other hand advice was not evidence based and could potentially be harmful. Equally, the search engine Google was identified as a superior way of asking questions so there may be little demand for a forum.

Privacy

Participants had mixed views about the acceptability of sharing of data with certain groups, and whether in identifiable or anonymised form. There were concerns expressed about continual location monitoring (GPS) as well as any microphone recordings. All participants were happy for their data to be made available for research in anonymised form, but with the caveat that the data was not sold for profit. Finally participants felt it was very important that they had ultimate choice on whether to share their data, and the ability to control this choice, e.g. start and stop sharing data whenever they wished.

Product Design

In terms of willingness to change medication or type of device, participants expressed a range of preferences and in general, a reluctance to change medication type. Participants were generally unwilling to change their mobile phone type as well. When considering secondary devices (e.g. wrist bands), some but not all participants would be willing to wear extra devices, but not necessarily all of the time. There was a request for the device to be fully waterproof, and a suggestion that a very small device that could be attached to existing things (e.g. watch or necklace) would be preferable to wearing an additional accessory. Inhaler design was generally not felt to be ideal; some participants commented that it was too large and bulky to fit in a pocket, whether it would be possible to make something flatter. One participant suggested they would like to substitute the inhaler entirely with another method, e.g. tablets. All groups noted that the product design needed to cater for all groups of people with asthma, not just the young, technologically-embracing demographic.

Goal Setting

There were mixed opinions about the usefulness of goal setting. Some participants felt it could help with adherence, and also that it could provide a visual record of how they were doing, and whether their asthma had improved.

Additional Functions

Additional functions suggested by participants included:

- The system linked to other apps, e.g. diet monitoring
- The system provided a way to log medication that was being taken for other co-morbidities and further identified if there were any interactions

3.5.1.2 Healthcare Professionals

Existing knowledge of mHealth and asthma, and any experiences or expectations of using it

All the HCPs were aware of asthma specific mHealth applications but none had either asked their patients to use them or had direct experience of a patient using them and sharing the data. One asthma nurse had experience of glucose home monitoring (for diabetes) and had seen this to be effective and there was agreement that home monitoring / self-monitoring had the potential to be beneficial for asthma. Some of the HCPs were aware of the inhaler chips that record compliance and were shortly about to start using these in a daily FeNO monitoring trial.

It was noted that not all patients will want to use mHealth, for a variety of reasons. Well controlled mild to moderates will likely view this as a burden whose limited benefit does not outweigh this burden, and older patients generally preferred face to face consultations as not all of them have smart phones or know how to use them.

There was an expectation that any mHealth system should not create significantly more work for HCPs. There was a worry that patients with severe asthma could receive messages to 'seek further medical advice' on almost a daily basis which would both worry the patient as well as increase the workload of HCPs.

Measurements that might help control asthma or prevent asthma attacks

Measurements that were felt could help control asthma or prevent attacks include:

- Tracking of peak flow
- Frequency of inhaler use
- Inhaler technique feedback
- Night time waking
- Stress, pollution, allergens and cough count could all be predictors of exacerbations, as would be the presence of a cold
- Linking prescriptions to GP records so that HCP can see how much medication is being collected. At a basic level if inhalers were being used more frequently than the patient was becoming less well controlled
- Symptom diaries for children and moderate to severe patients (it was felt that other groups would not be motivated to complete these)
- Collecting a range of measurements would be helpful to understand more about the type of asthma in adolescents and newly diagnosed patients.

Burden of automated data

There were concerns expressed that 'normal' was different for everyone and therefore settings and ranges needed to be established on an individual basis. Most patients have additional comorbidities and data related to these would presumably not be measured; consequently an automated interpretation of the data may not provide accurate advice. Additionally, if the time it takes to personalise the system to each patient is too great, then HCPs will not adopt the system.

Burden of lung function measurements

It was felt that if peak flow monitoring could be linked to an app so that the result was transferred automatically instead of being inputted manually, this would increase compliance with daily testing. With more complex lung function tests, there were concerns that patients would not have the correct technique to generate an accurate result. One HCP commented that they took 12 attempts to correctly use a FeNO machine at a recent conference, and that after 6 consecutive attempts it would no longer be possible to get an accurate reading. In addition, dysfunctional breathers may struggle to use these devices unsupervised. One nurse commented that there was a risk that patients became institutionalised if they were asked to continually measure lots of different things.

Burden of inputting data

There was discussion that in the past, daily self-monitoring had been requested via the use of a booklet / journal. However, the HCPs experience was that most patients completed several weeks' worth of data on the day of their appointment, making the data subject to bias recall and affected its accuracy. There was a concern that if patients were asked to record too many things, they would start making them up, which was a waste of time at best, and potentially could lead to the wrong medical advice being given.

Symptom diaries were felt to have the potential to be useful, but it had to be noted that these were a subjective measure and not always correlated with objective measures such as lung function. Therefore their usefulness may be limited.

The HCPs expressed concern that patients who wished to disengage from their condition may learn what data / readings to input in order to get the advice messages they required. Similarly, those who wished to see a HCP more frequently may perform tests in such a way that prompts a message to seek additional medical advice. Every patient has an individual set of beliefs and expectations about their condition, and these influence their psychological behaviours in a way that is entirely uncorrelated to any physiological measure of their condition. For this reason the HCPs felt that data monitoring should be for short periods of time rather than continuously, and that only certain patients should be selected to do this, based on the HCPs assessment that the exercise will contribute positively to that person's management of their asthma.

Alerts and reminders

Useful reminders might include advising an increase in dose when exposed to triggers (e.g. pollen season), and reminders to start and stop antibiotics. Reminders would generally be used to increase adherence and HCPs felt that reminders would be particularly useful for transitioning patients and those moving away from home for the first time, particularly as they don't often register with a new HCP in their new location.

Recommendations and User Feedback

There was concern expressed that some patients who (for whatever reason) wished to either increase or decrease their medication would learn what data to input to generate these recommendations, and this could be dangerous if their own healthcare team is not aware of this. Conversely, some patients would only follow instructions from their own doctor and would ignore anything that contradicts these. Recommendations to seek further advice from an HCP could be very valuable for patients who are not feeling well but didn't want to waste the HCP's time as it allowed exacerbations to be treated earlier.

Another issue raised was the potential of legal implications of any harm caused to a patient based on recommendations from the system and who would be responsible for this. On balance it was felt that recommendations to seek further medical advice were acceptable but changes to medication were not.

Privacy

The HCPs questioned the confidentiality of data held on individual's mobile devices and whether it could be made non-identifiable or whether they could be sued if it was accessed by someone else (e.g. via Bluetooth).

Product Design

The HCPs were in agreement that the system should only monitor three of four things and these should be selected based on the individual (from a longer list of options). It was felt that an overly complex system would not be used consistently or long-term and therefore less value would be gained than if a small number of selected options were monitored.

Goal Setting

HCPs thought that goal setting would work for some, but not all patients, and would perhaps be more successful in the short and medium term than long term as people were generally more motivated over shorter, finite periods of time. For example, most patients stopped monitoring their peak flow within two weeks of starting.

The inclusion of fitness, exercise and diet trackers was felt to have benefit in terms of helping asthmatics lose weight as this generally correlated with an improvement in their condition (and many other co-morbidities). HCPs felt that the key challenge here would be motivating the patient to use the app effectively and goal setting could help with this.

Additional Functions

Further suggested functions included:

- A mobile app with the patients' own asthma treatment plan on it, that could be accessed without the need for a pin-code
- An educational tool that can provide more information and reinforced what the HCPs have told them
- An effective way to recording side effects as it was hard to recall specifics at an annual consultation

3.5.2 Findings from surveys

The overall aim of the focus groups and surveys was to determine the opinions of people with asthma and healthcare professionals (HCPs) on the functionality of mHealth systems to support asthma self-management. The surveys enabled quantification of the opinions generated during the focus groups. Two surveys were produced asking questions around mHealth and measurements, the burden of inputting data, alerts, reminders, recommendations, user-feedback, privacy, product design, goal setting and additional functions. These surveys can be viewed in full in Appendices 4-5 at the end of the Deliverable. This section of the report will analyse the responses of 57 healthcare professionals and 168 people with asthma.

3.5.2.1 Patients

Analysis of patient survey

Out of 168 respondents, 74% were female and 26% male. The average age was 39.7 years old with the majority ethnic origin being White British at 81% of respondents. There was a large spread of location, with respondents in Scotland, Wales, Northern Ireland and from across England and London. One respondent was from Belgium and another from France who could have been part of EFAs network of people with asthma. The survey had an 83% completion rate.

Questions were initially asked to ascertain the respondent's level of asthma based on the asthma control questionnaire (ACQ). Questions such as how often their asthma woke them in the night (81% answered never to a few times); what the level of symptoms were on waking (68% none to mild); how limited activities were (71% not limited at all to slightly); how short of breath they felt in the last week (61% none to a little); how often they wheezed (73% never to a little); how many puffs of their inhaler they had per day (79% 1-4 puffs) and whether the respondents had had a severe asthma attack in the last year (45.5% yes, 54.5% no). Severe asthma attacks are defined by the occurrence of the following: Use of systemic corticosteroids (tablets, suspension or injection) or an increase from a stable maintenance dose, for at least 3 days or a hospitalisation or A&E visit because of asthma which required systemic corticosteroids

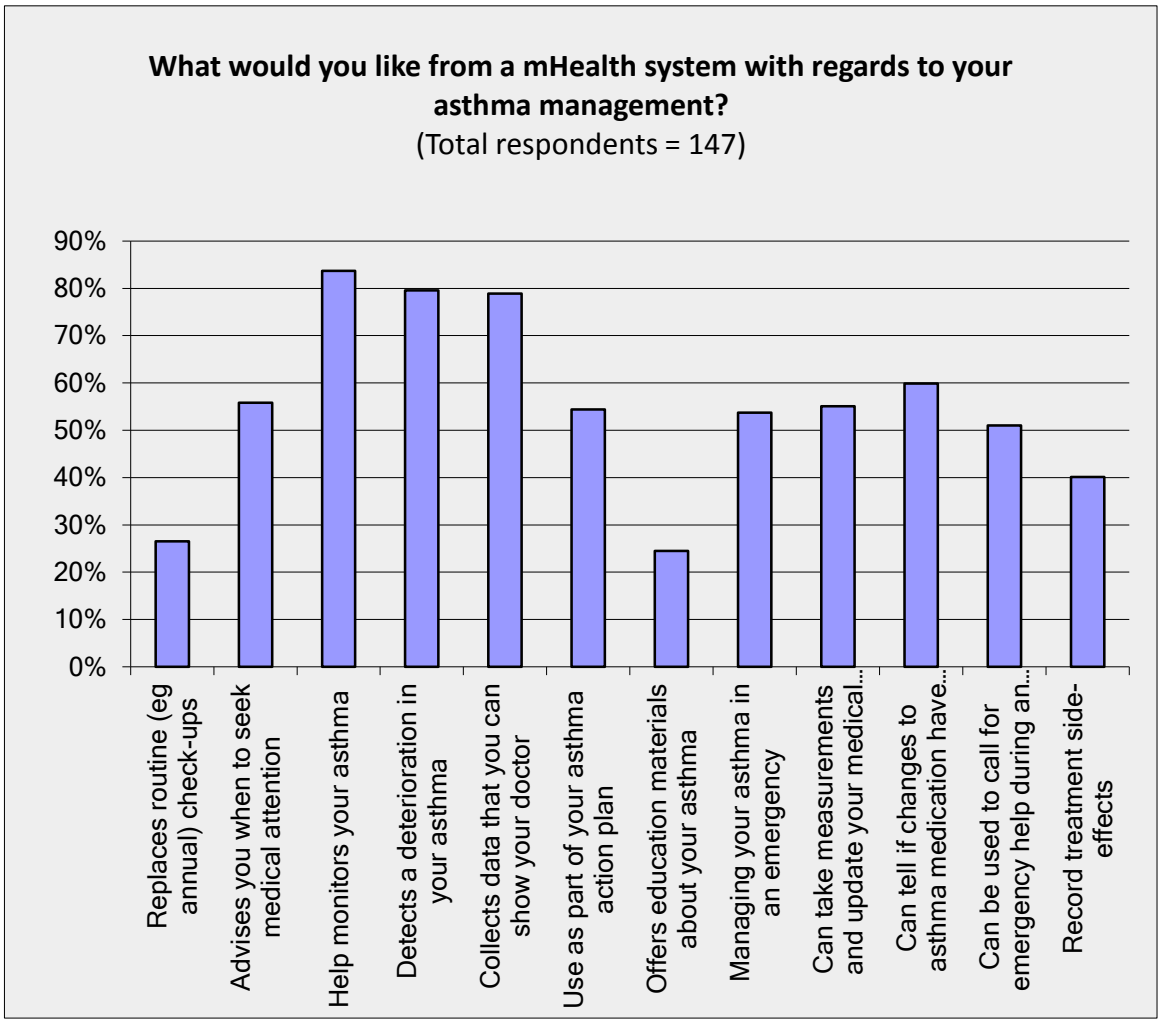


Figure 2: Requirements of people with asthma of a mHealth system

People with asthma were asked what they would like from a mHealth system. The options which 80% of respondents chose were a device which helped them monitor their asthma, one that detects deterioration in their asthma before they would necessarily notice it, and one that can collect data which they can show to their healthcare professional to demonstrate how their asthma has been. Between 50%-60% of respondents wanted a system which can tell them if changes to asthma medication have improved their asthma, when to seek medical attention, can take measurements and update their medical records, to use as part of their asthma action plan, how to manage their asthma in an emergency and a device which can be used to call for emergency help during an asthma attack. Only 25% of people with asthma wanted a system which replaced routine check-ups and one that offered educational materials about their asthma.

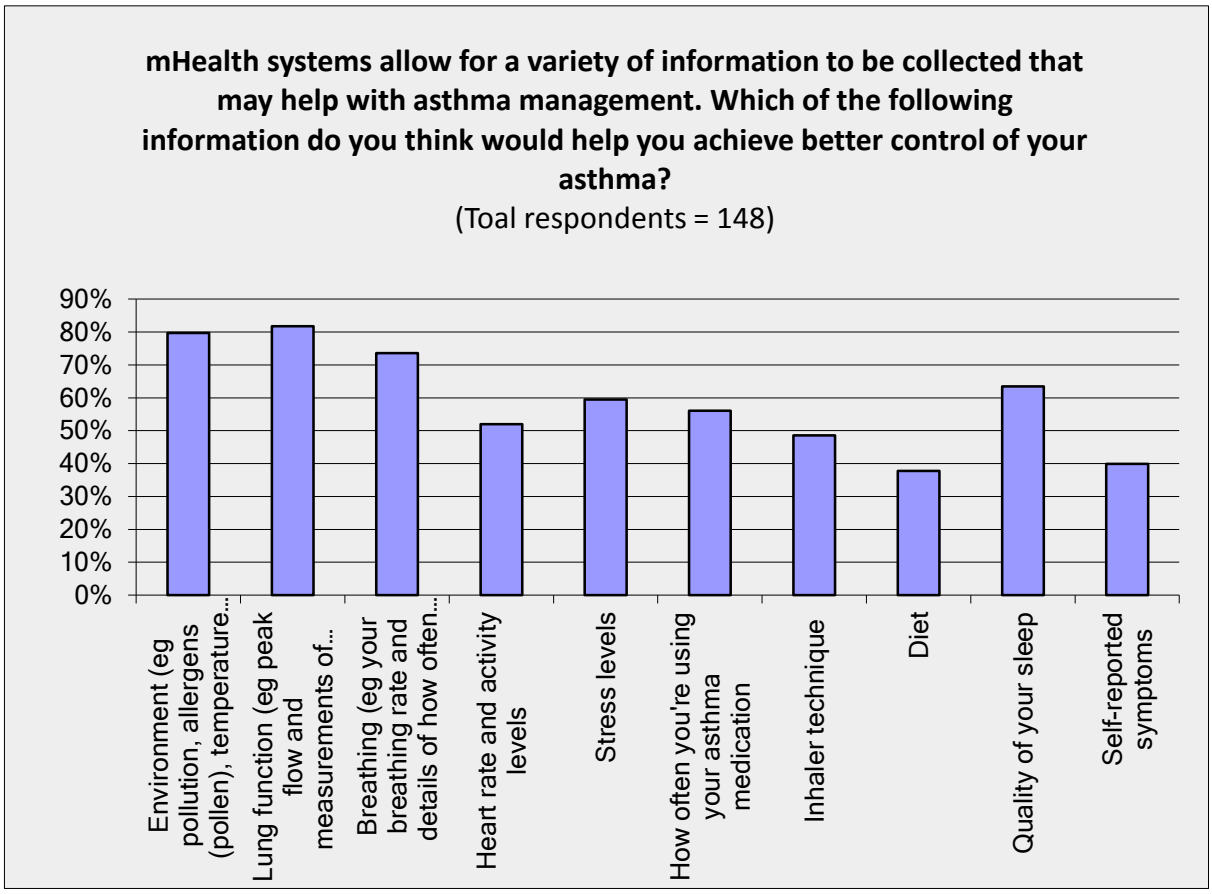


Figure 3: Factors to monitor which may improve asthma control

80% of respondents felt that having information about their lung function (e.g. peak flow and airway inflammation) and their environment (such as pollution levels and allergens) would help them achieve better control of their asthma. 74% thought knowing their breathing rate and how often they cough would be beneficial. Between 50%-60% of respondents thought having information about their heart rate, activity levels, stress levels, frequency of using asthma medication, inhaler technique and quality of sleep would help them achieve better asthma control. Diet and self-reported symptoms were considered by fewer respondents (40%) to help achieve asthma control.

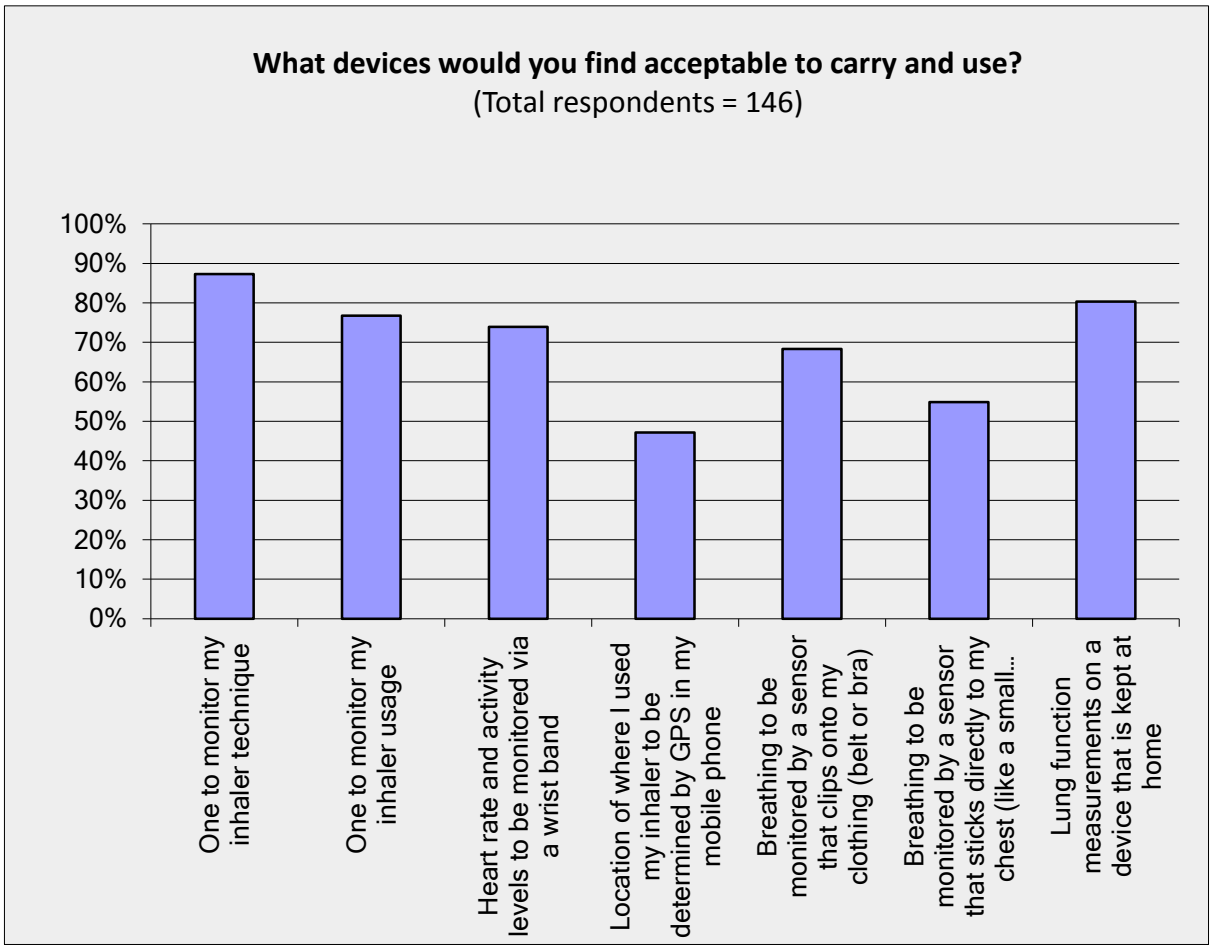


Figure 4: Acceptable additional devices people with asthma would carry and use

Some mHealth systems could take measurements 'automatically'. This means that patients wouldn't have to do anything to allow the measurement to be taken. For these measurements to be collected they may need to wear or carry an additional device. As can be seen from the responses above, the device fewest respondents found acceptable would be one to track location determined by GPS on a mobile phone. In comparison, nearly 90% of respondents thought that a device attached to their inhaler to monitor their inhaler technique would be acceptable to carry and use.

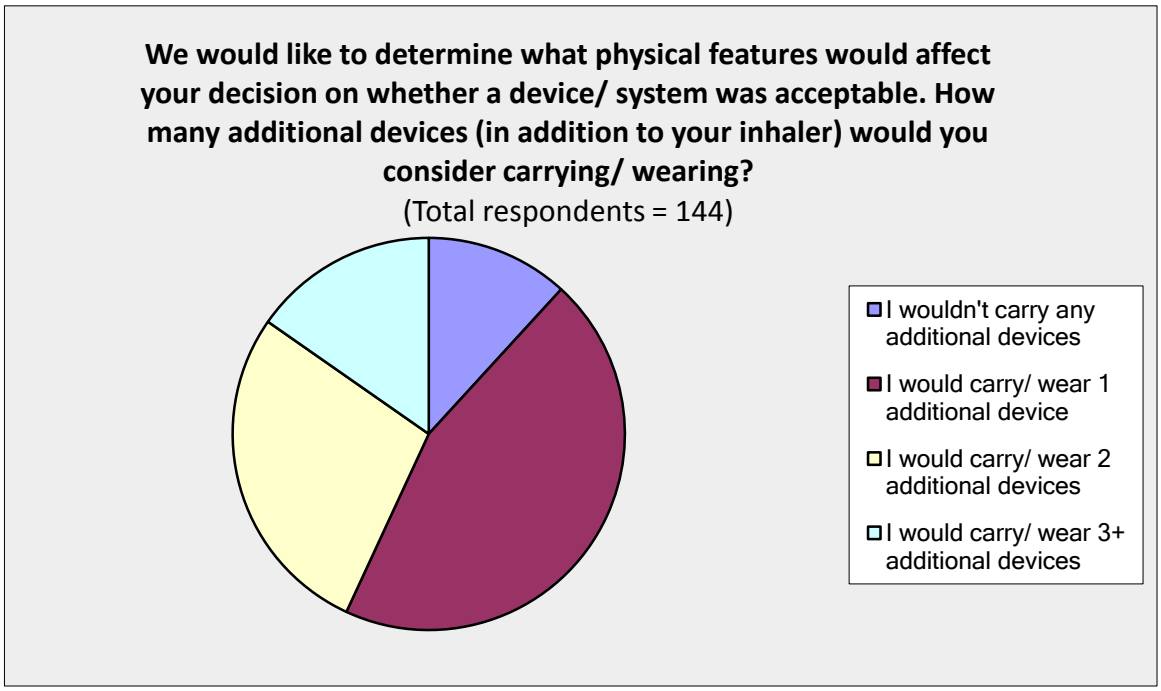


Figure 5: Number of devices patients find acceptable to carry in addition to their inhaler

73% of respondents would be happy to carry one or two devices in addition to their inhaler. 15% would be happy to carry three or more and 12% wouldn't want to carry any additional devices.

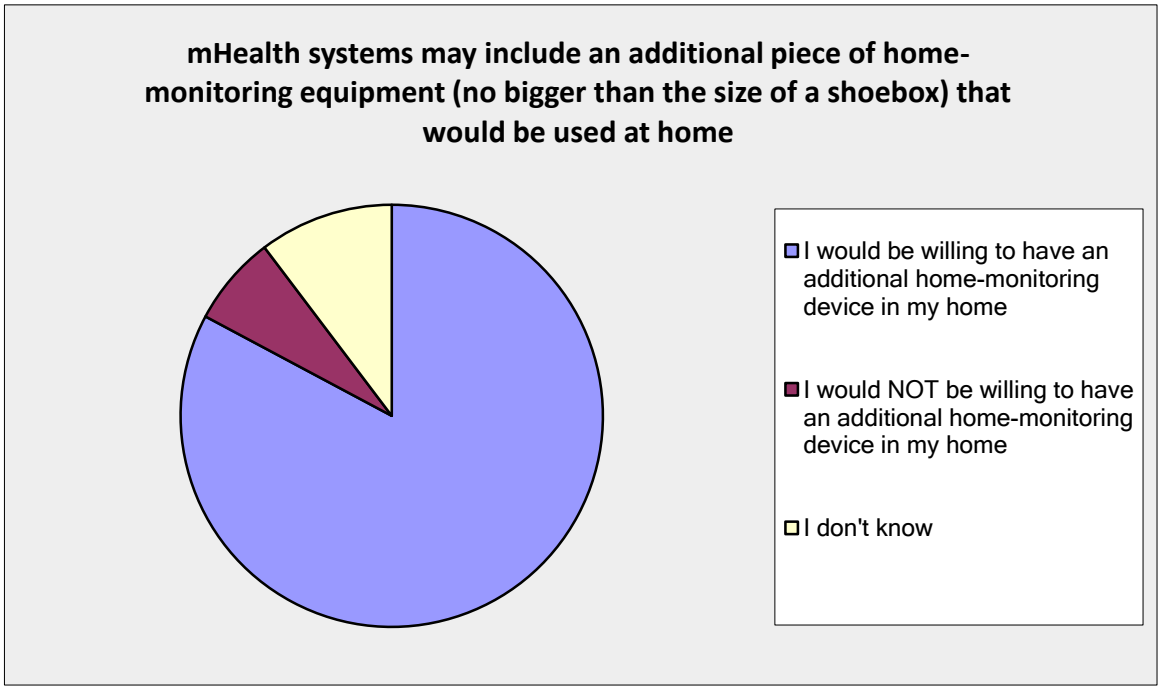


Figure 6:.Willingness to accommodate a larger device at home

83% of respondents would be happy to have an additional home-monitoring device, which would be no bigger than a shoebox that could be used at home. 7% stated that they wouldn't be willing to have an additional home-monitoring device and 10% of respondents did not know.

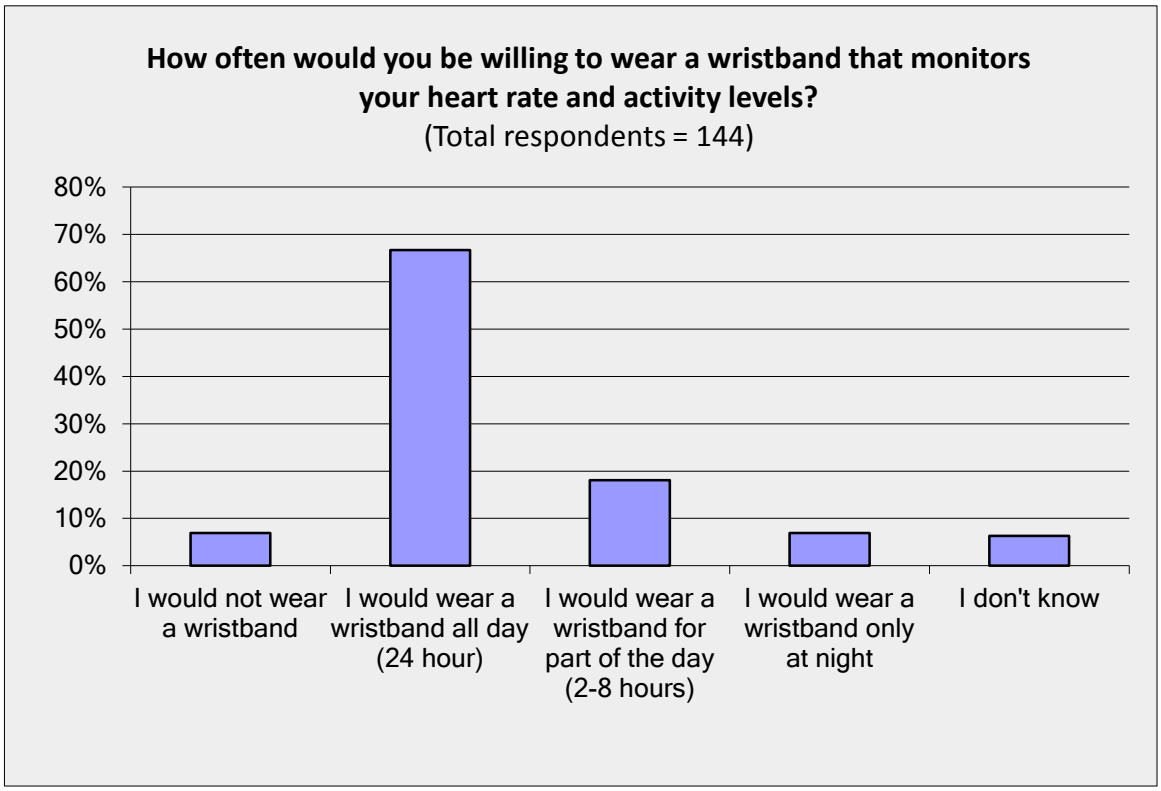


Figure 7: Duration people with asthma would be willing to wear a wristband to measure heart rate

67% of respondents would be willing to wear a wristband which monitors their heart rate and activity levels all day (24 hours). 18% stated they'd be willing to wear the wristband for part of the day (between 2-8 hours) and 7% of respondents would only wear a wristband at night. 7% wouldn't wear a wristband at all.

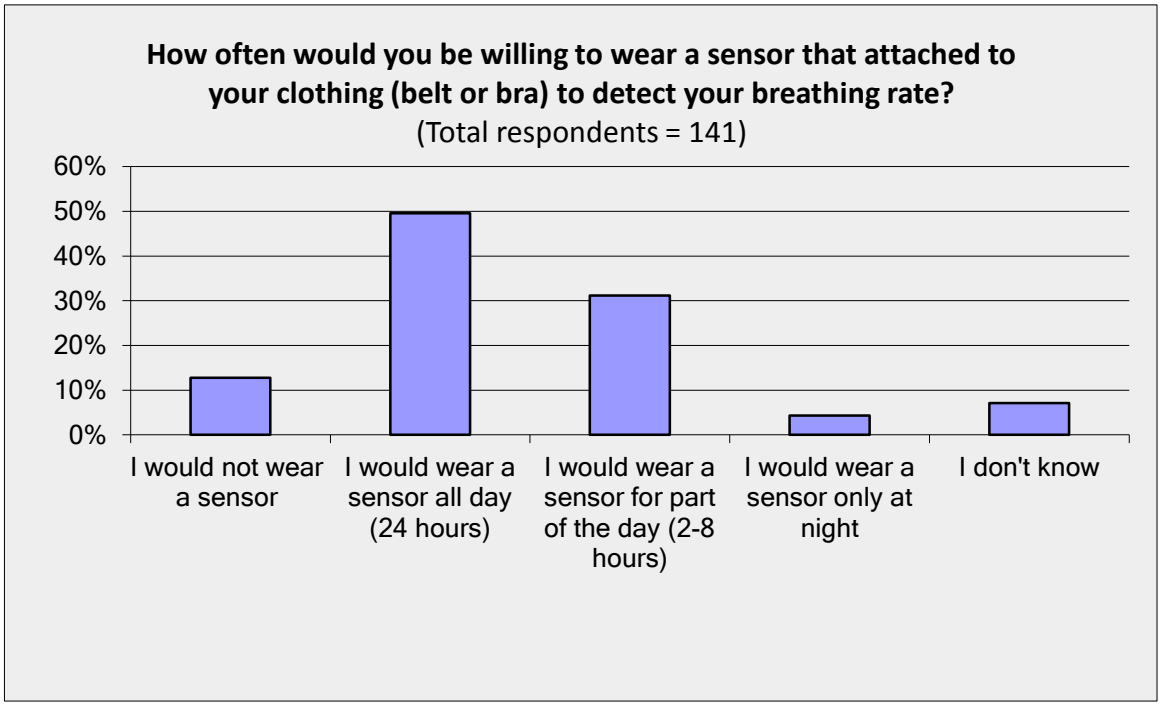


Figure 8: Duration respondents would be willing to wear a breathing rate sensor

The results of attaching a sensor to clothing are very similar to that of the wristband. 50% of respondents would be willing to wear a sensor attached to their belt or bra all day (24 hours) with 31% willing to wear it for part of the day (2-8 hours). 4% would

wear the sensor at night only and 13% would not wear a sensor attached to clothing at all.

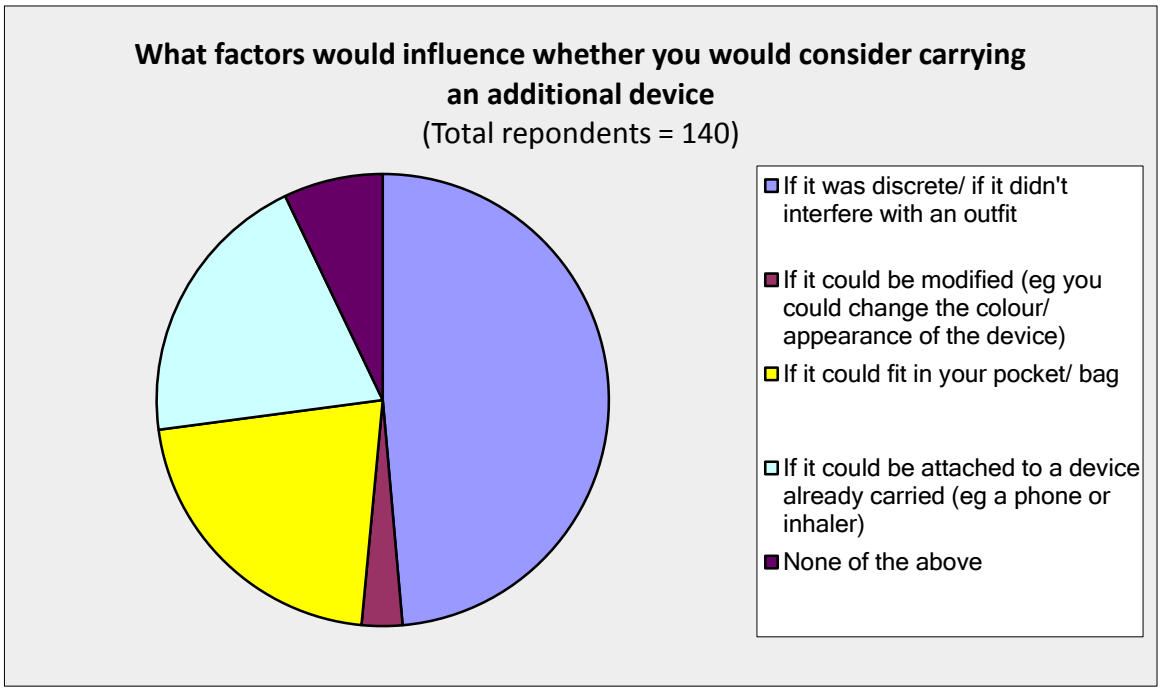


Figure 9: Factors which would influence whether an additional device would be carried

The factor which would most influence whether people with asthma would be willing to carry and additional device was if it was discrete and didn't interfere with an outfit. 20% of respondents felt that being able to fit the device into a pocket or bag and if it could be attached to a device already carried (such as a phone or inhaler) would be factors.

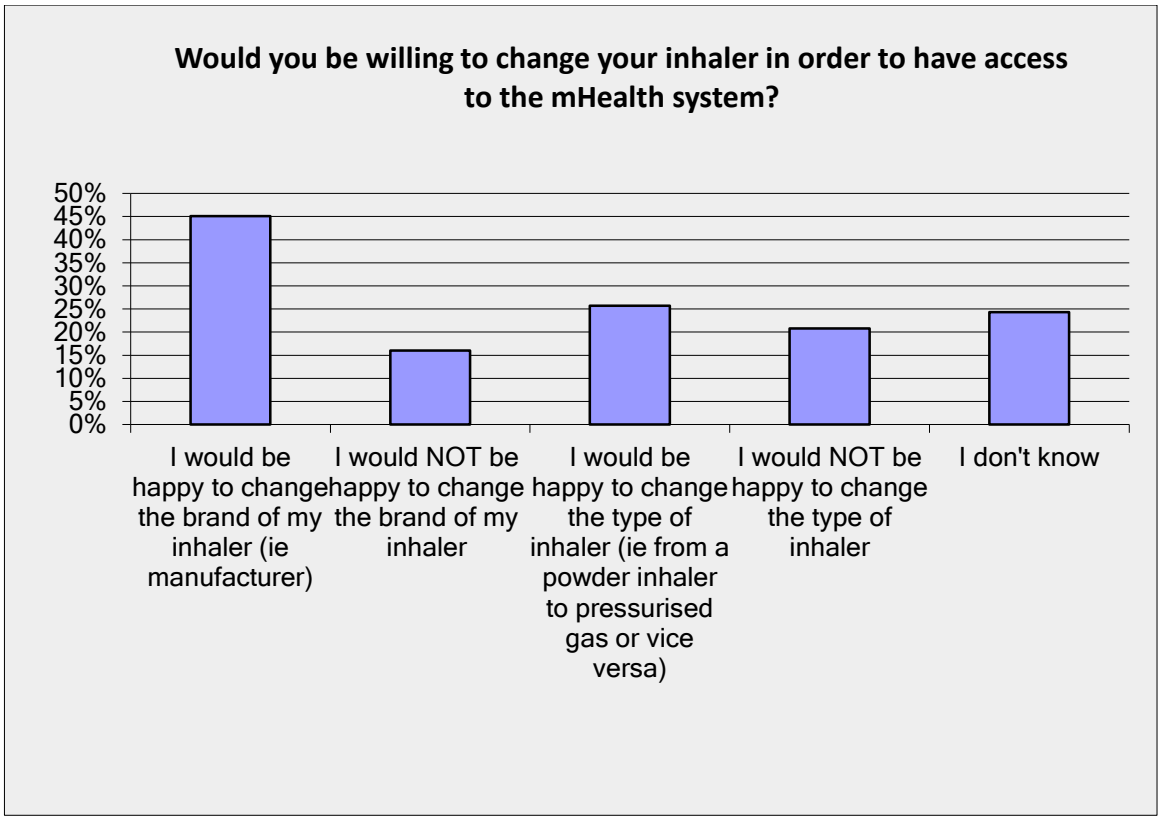


Figure 10: Willingness to change inhaler in order to have access to the mHealth system

70% of respondents would be willing to change the brand (i.e. manufacturer) and the type (powder to pressurised gas) of their inhaler to have access to the mHealth system. 47% would not be happy to change either the brand or type of their inhaler.

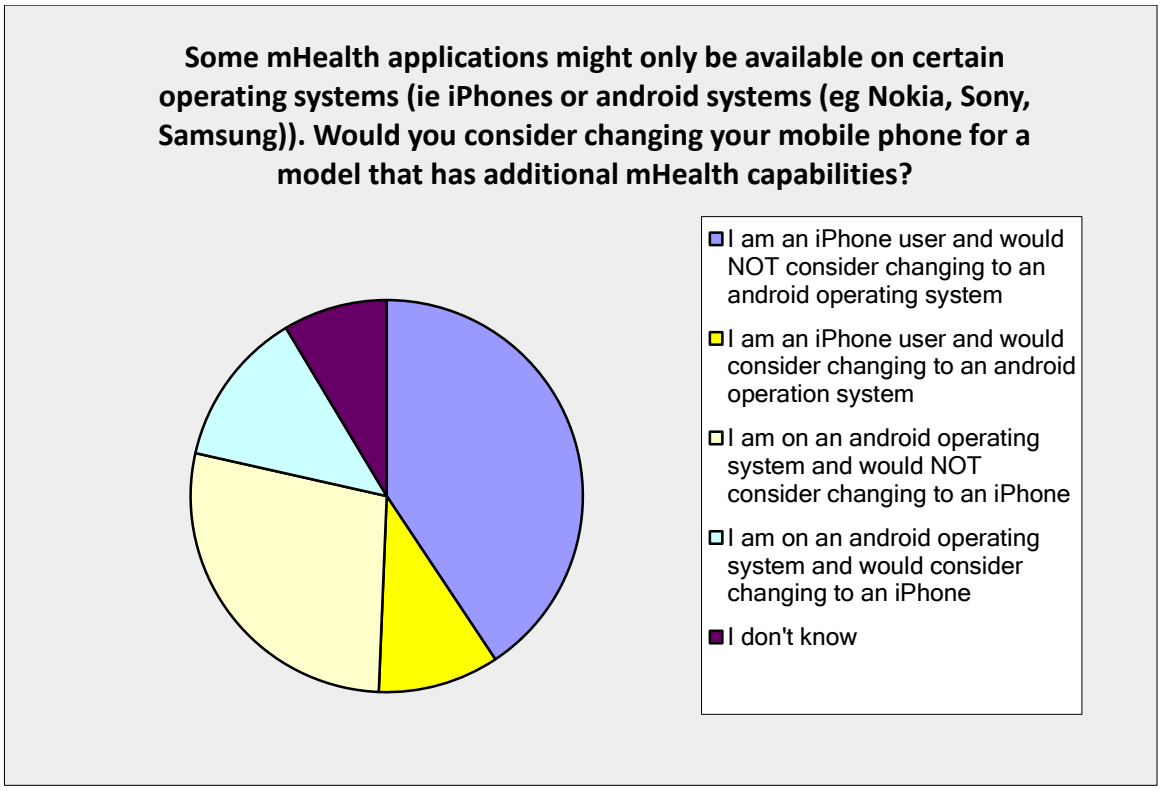


Figure 11: Willingness to change mobile phone model / operating system

Figure 11 shows that respondents with either iPhones or android systems were more likely to refuse to change operating system / phone than be willing to change. Only 20% of iphone users and 32% of android users would be willing to change operating system.

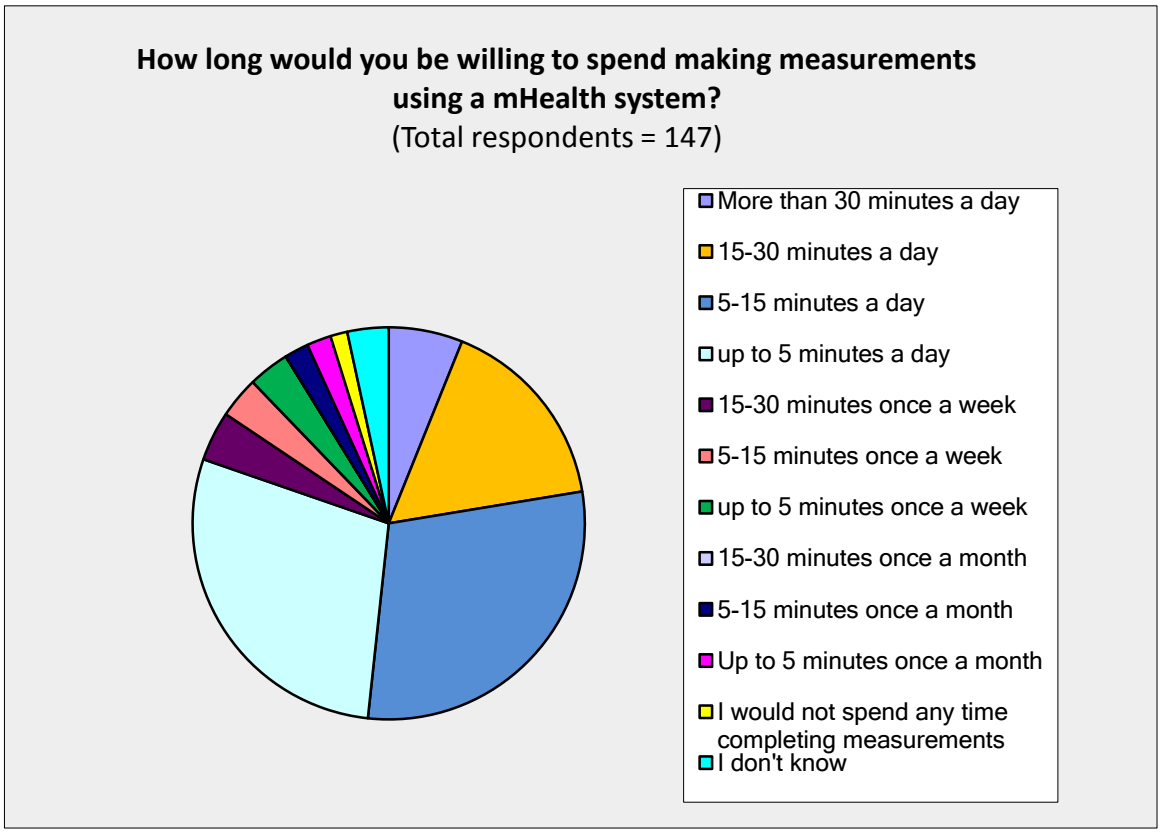


Figure 12: Duration respondents would be willing to spend making measurements

Some measurements made using the mHealth system may take some time to complete (e.g. lung function measurements and completing questionnaires). Respondents were asked how long they would be willing to spend taking measurements for this system. An equal number of respondents (29%) would be willing to spend up to 5 minutes per day and between 5-15 minutes per day. 16% would be happy to spend 15-30 minutes with 6% happy to spend more than 30 minutes per day taking measurements. Between 2% and 4% of respondents would be willing to spend less time taking measurements with 1% not willing to take any.

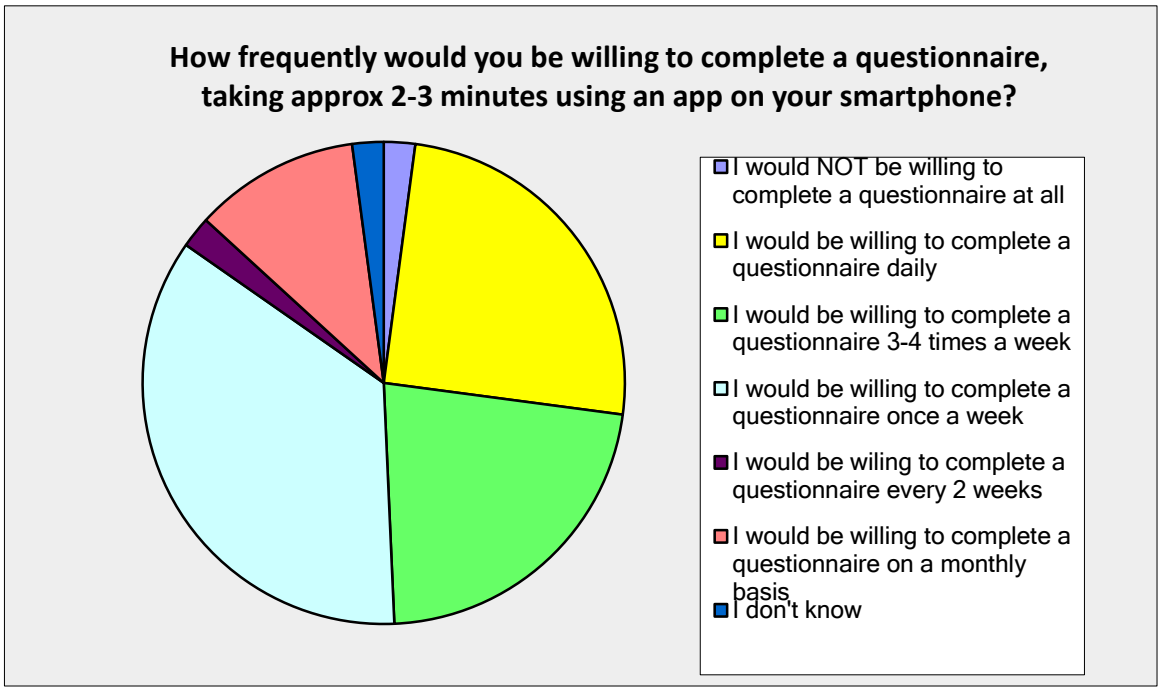


Figure 13: Frequency respondents would be willing to complete a questionnaire using a smartphone app

The largest percentage (35%) of respondents would be willing to complete a questionnaire once a week. Between 22% and 25% of people would be happy to complete a questionnaire either daily or 3-4 times a week, with 11% willing to complete on a monthly basis.

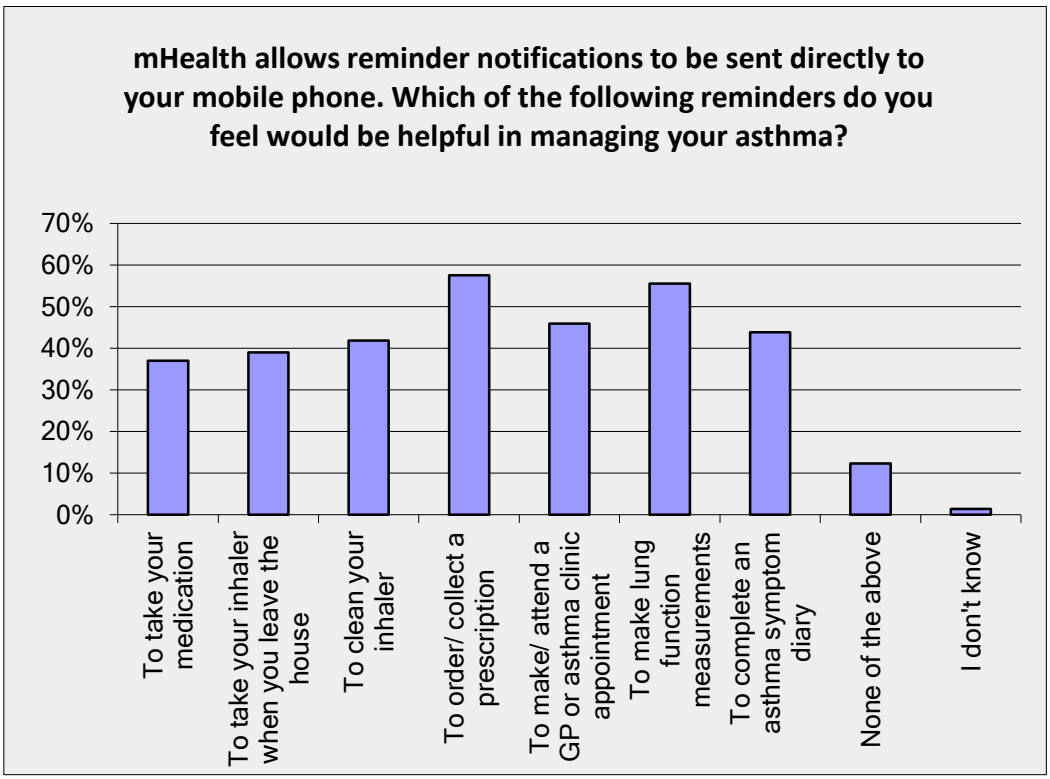


Figure 14: Helpfulness of reminders in the self-management of asthma

58% of respondents thought that having a notification to remind them to order or collect a prescription and to take lung function measurements would be most helpful in

managing their asthma. Between 37% and 45% of respondents thought that reminders to take their medication, remember their inhaler when leaving the house, to clean their inhaler, to complete an asthma symptom diary and to make or attend a GP/ asthma clinic appointment would be helpful in managing their asthma.

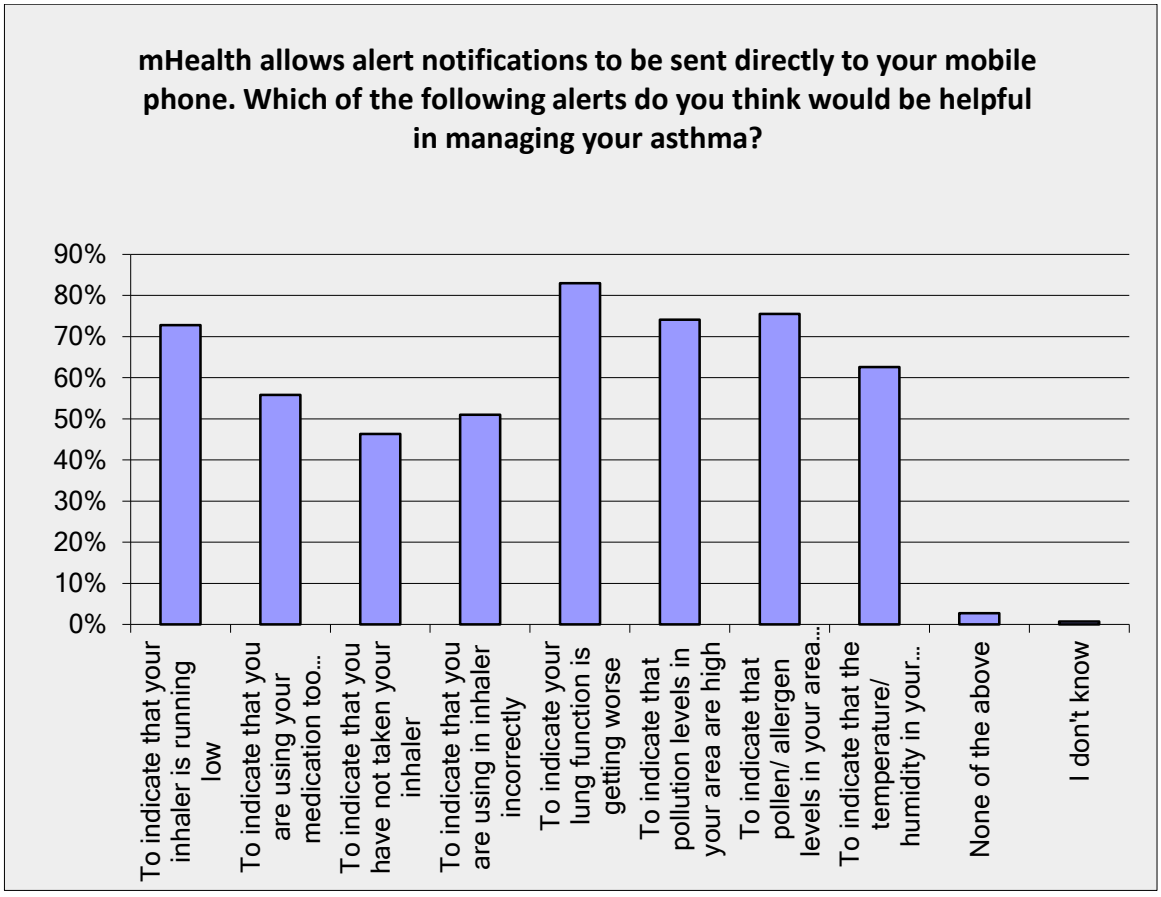


Figure 15: Alerts which could be helpful for the self-management of asthma

Alerts to indicate that the respondent's inhaler is running low, that their lung function is getting worse, that pollen and pollution levels in their area is high and that indicate their lung function is getting worse were all deemed to be the most helpful in managing their asthma. Between 50%-60% of respondents thought alerts to indicate they are taking their medication too often, using their inhaler incorrectly and that indicate temperature and humidity in their area would be helpful in managing their asthma. 46& of respondents thought that an alert to indicate they haven't taken their inhaler would be helpful.

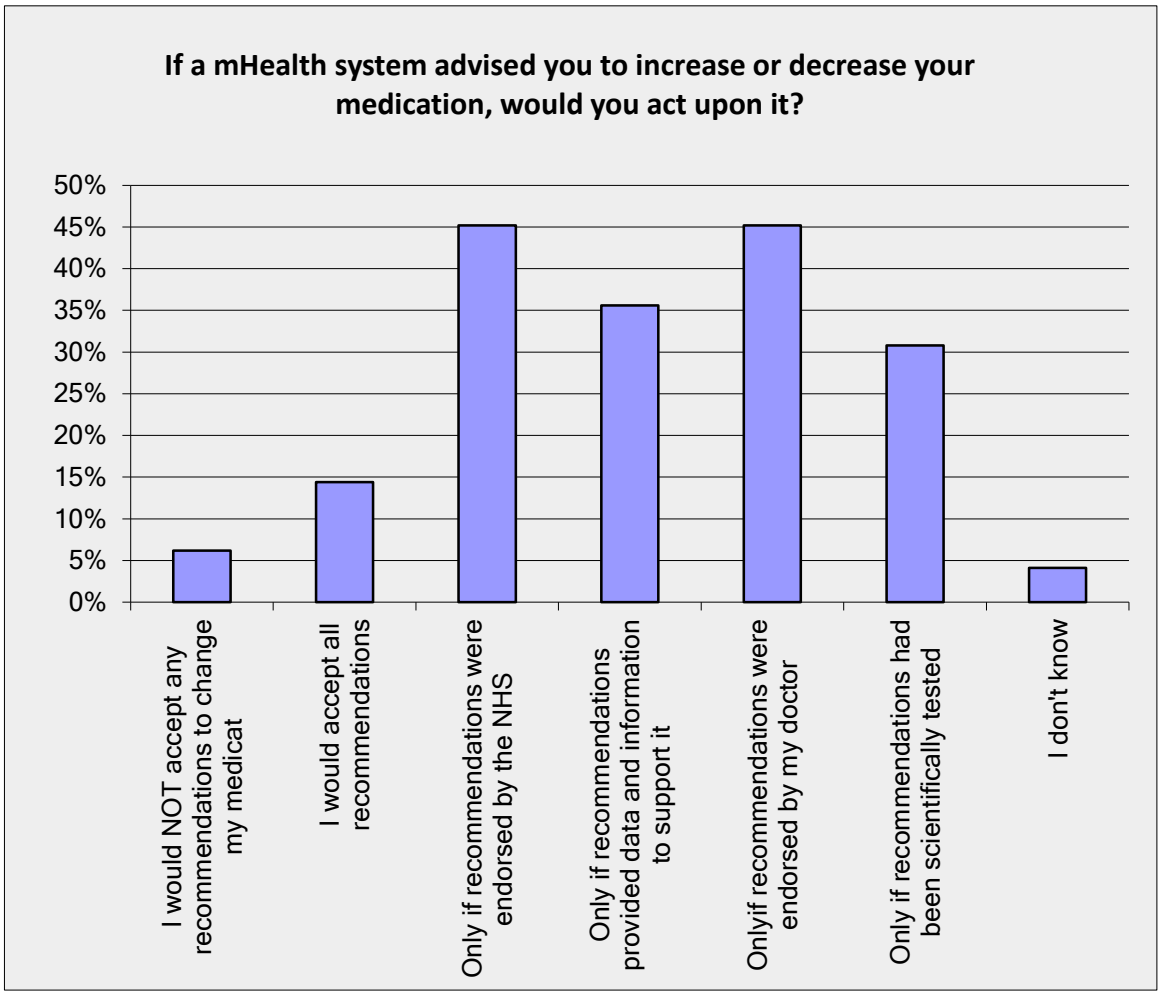


Figure 16: Propensity to act upon advice given by the mHealth system

mHealth systems can provide patients with feedback and recommendations based on the analysis of various measurements. This feedback may include the suggestion to step-up or step-down their medication or to visit their GP. 45% of respondents would act upon the mHealth recommendations only if the system was endorsed by the NHS and/ or their doctor. Between 30% and 35% would act upon a recommendation if data was provided to support it and only if the recommendations had been scientifically tested. 14% would accept all recommendations and 6% would not accept any recommendations to change their medication.

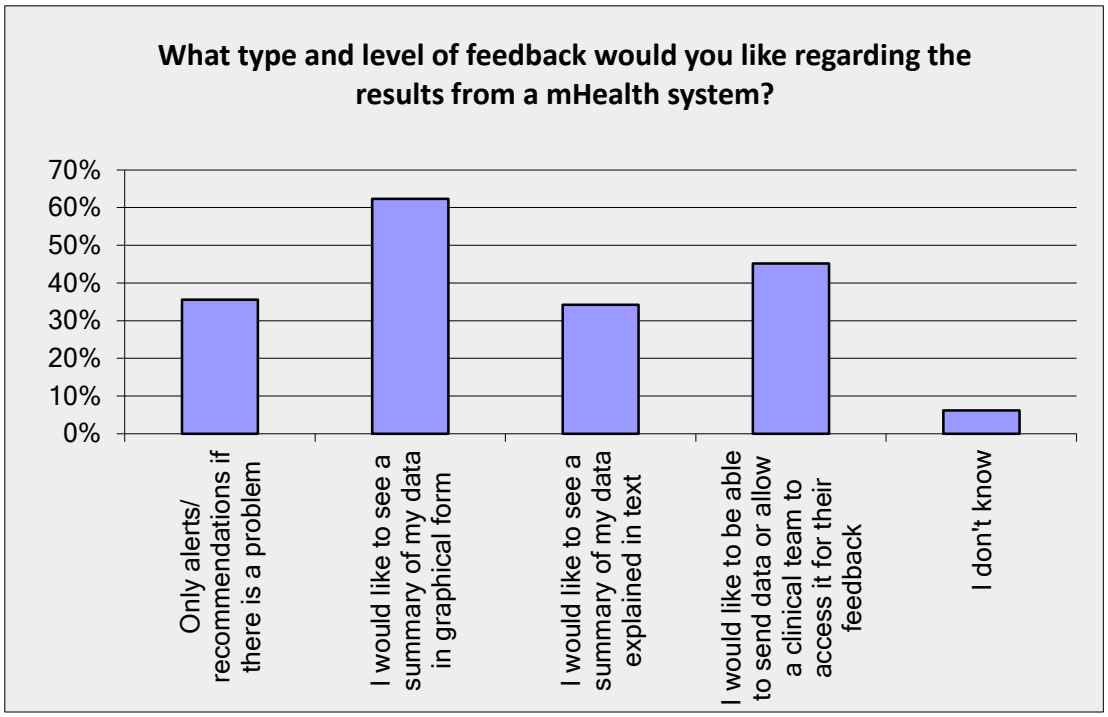


Figure 17: Feedback preferences of a mHealth system

Most respondents would like to see a summary of their data in graphical form, followed by being able to send data or allow a clinical team to access it, receiving alerts and recommendations only if there is a problem and to see a summary of their data explained in text.

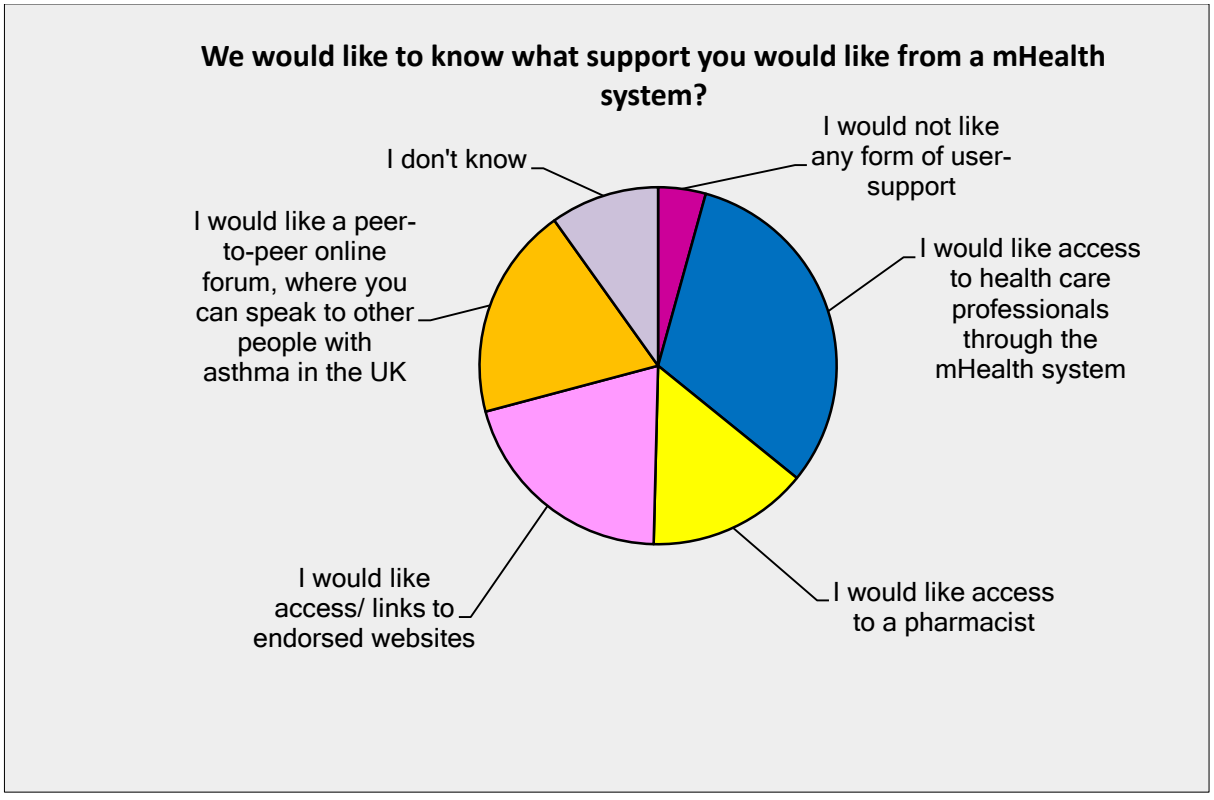


Figure 18: Support preferences of a mHealth system

56% of respondents would like access to healthcare professionals through the mHealth system. Between 24% and 35% would like access to a pharmacist, access to endorsed websites and a peer-to-peer online forum where they could speak to other people with asthma. 8% would not like any form of user-support.

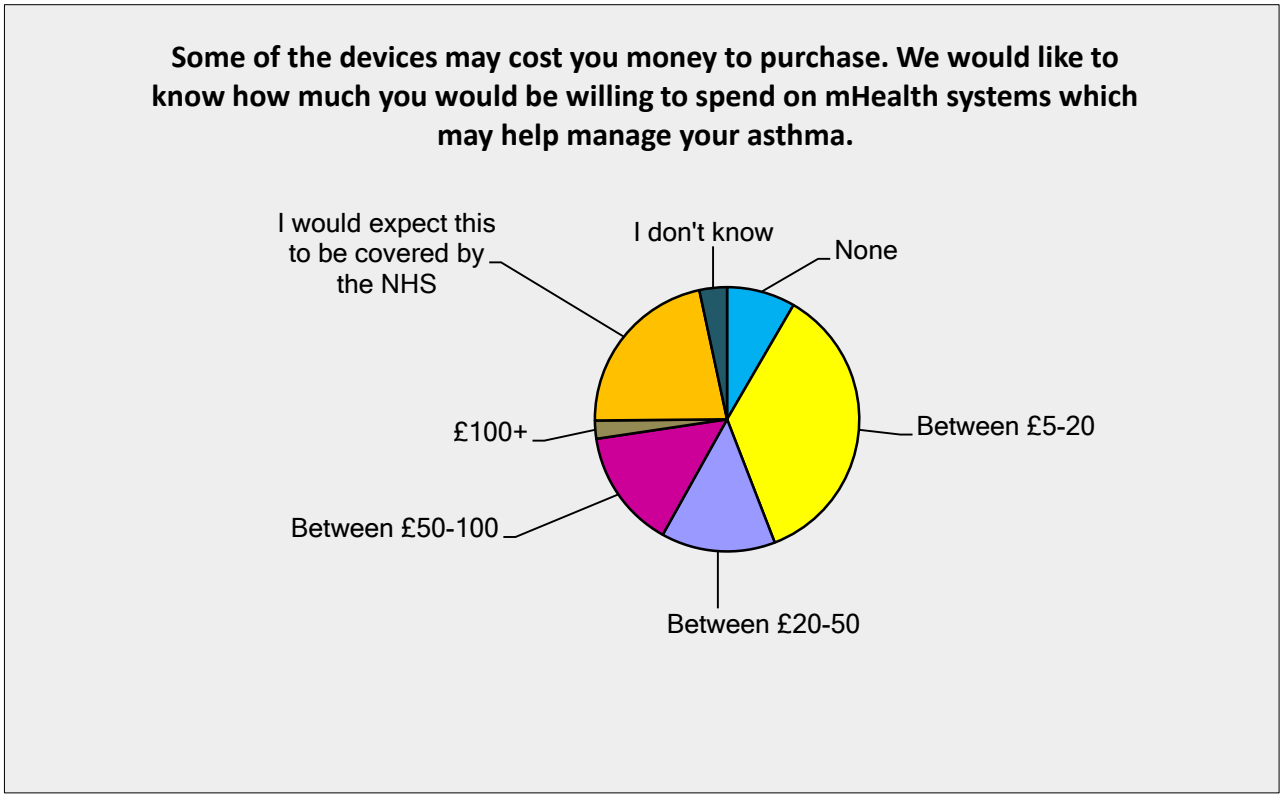


Figure 19: Willingness to spend money on a mHealth system

44% of respondents would be prepared to spend between £5-20 on a mHealth system to help manage their asthma. 27% felt that the cost should be covered by the NHS, 17% of respondents would be prepared to spend between £20-100 and 10% wouldn't be prepared to spend anything.

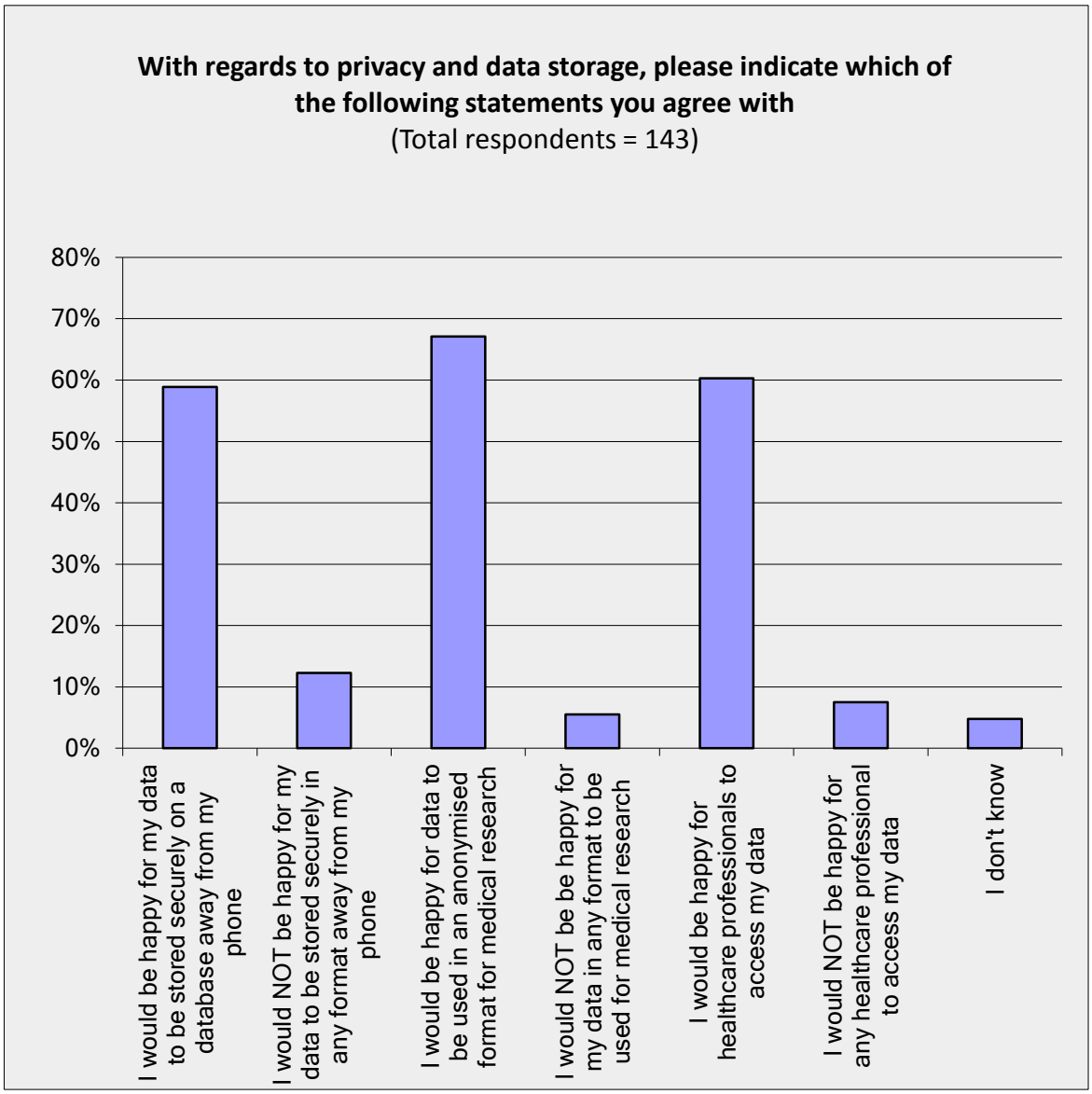


Figure 20: Data storage and privacy requirements

Over 60% of respondents would be happy for their data to be stored securely on a database away from their phone; for their data to be used in an anonymised format for medical research and for healthcare professionals to have access to the data. Between 6% and 12% of people would not be happy with the above data storage.

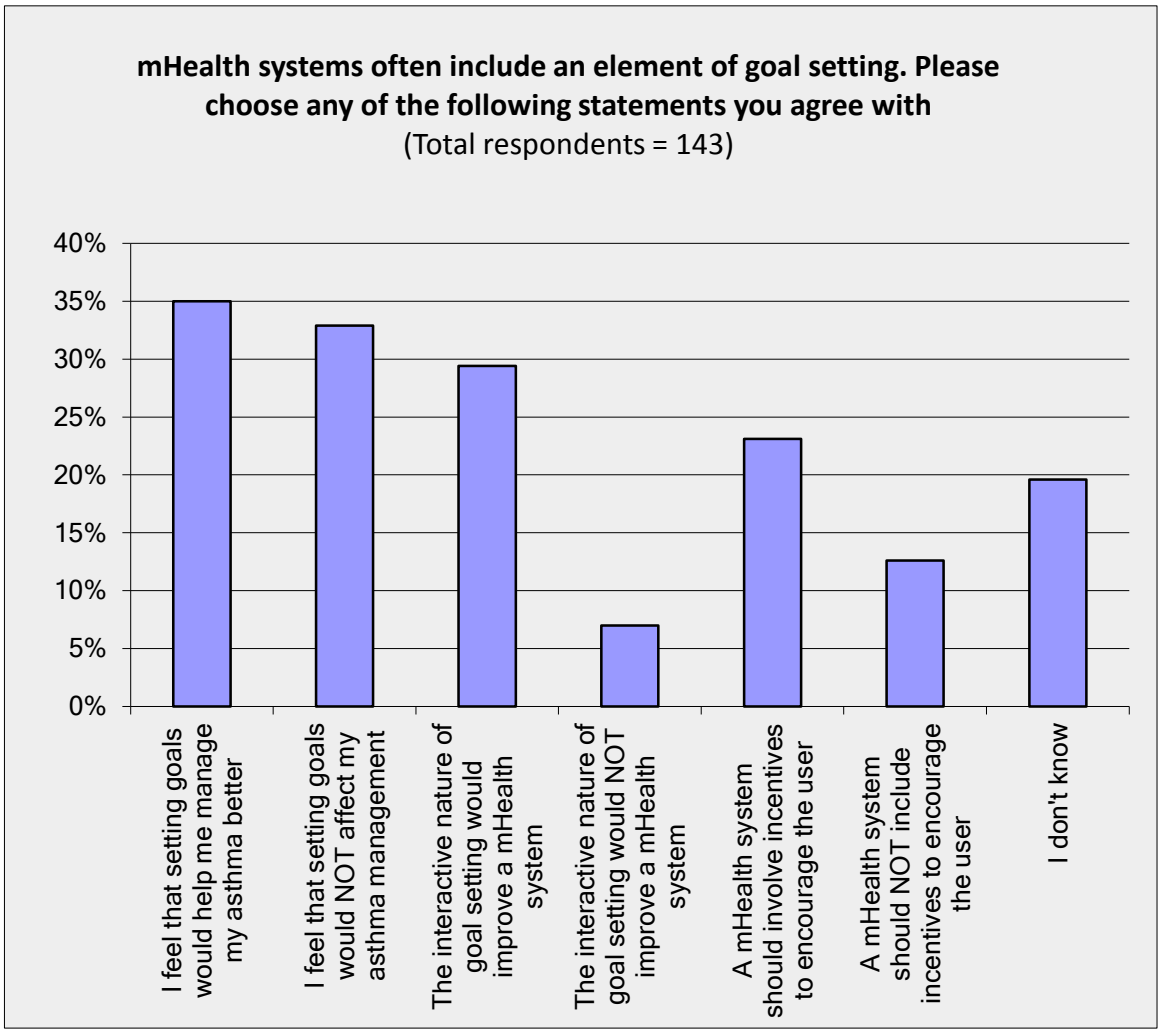


Figure 21: Respondents' opinions on goal setting for mHealth systems

35% of respondents felt that setting goals would help them manage their asthma better. A similar percentage felt the opposite, that setting goals would not improve their asthma management. 29% thought that the interactive nature of goal setting would improve a mHealth system and 23% felt that the system should have incentives to encourage the user.

3.5.2.2 Healthcare Professionals

Analysis of the Health Care Professional (HCP) survey

In total, 57 healthcare professionals who treat people with asthma responded to the survey, which was over the target of 50. 60% of these were female and 40% were male. 75% were white British, 14% were Indian, 3.5% white Irish and Pakistani with 1 respondent Bangladeshi and 1 'other' White nationality. 41.1% of respondents considered themselves an asthma specialist compared to 58.9% of HCPs who didn't.

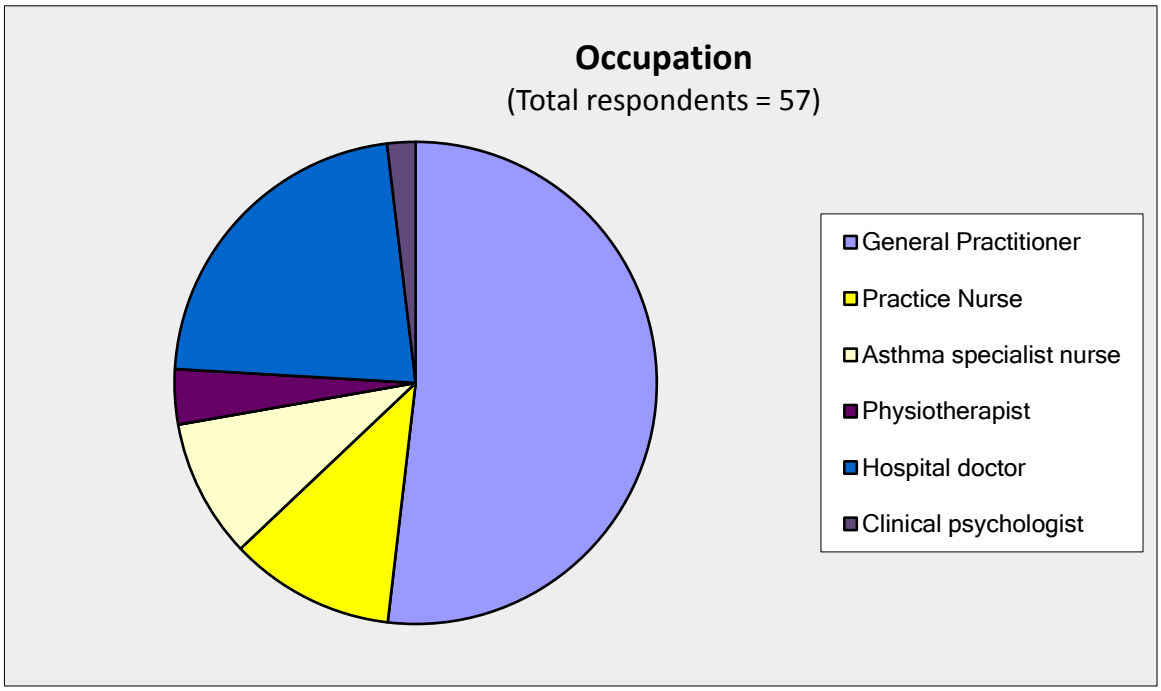


Figure 22: Occupation of Healthcare professional respondents

As can be seen from Figure 22, the majority of respondents (52%) were GPs. The next largest group were hospital doctors (22%), followed by practice nurses (11%), asthma specialists nurses (9%), two physiotherapists and one clinical psychologist. They were largely from the Manchester, Preston, Liverpool and London areas. This is largely due to the recruitment methods used.

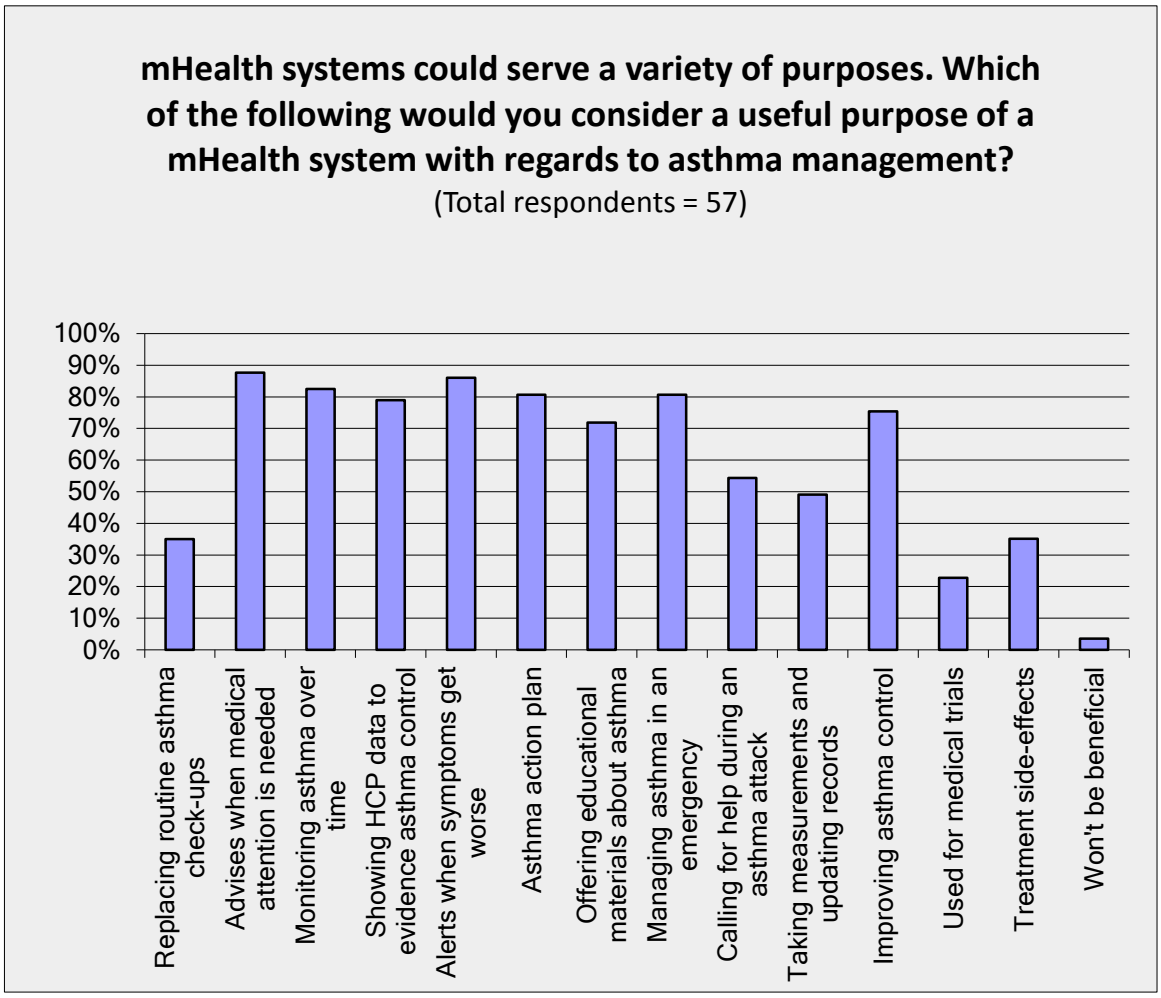


Figure 23: Potential uses of the mHealth system

HCPs were asked what they considered were useful purposes of the mHealth system. They were given a list of 14 options and could choose as many as they wished. The choices which HCPs thought would be least useful to people with asthma were the mHealth system replacing routine asthma check-ups, being used for medical trials and recording treatment side effects. Only 4% of respondents thought that the system wouldn't be beneficial at all. Between 70-80% of HCPs thought that advising when medical attention is needed, monitoring asthma symptoms over time, being able to show HCPs data to demonstrate how their asthma has been, alerts on worsening symptoms, providing an asthma action plan, offering education materials about asthma and whether changes to medication has improved asthma control all useful purposes of the system.

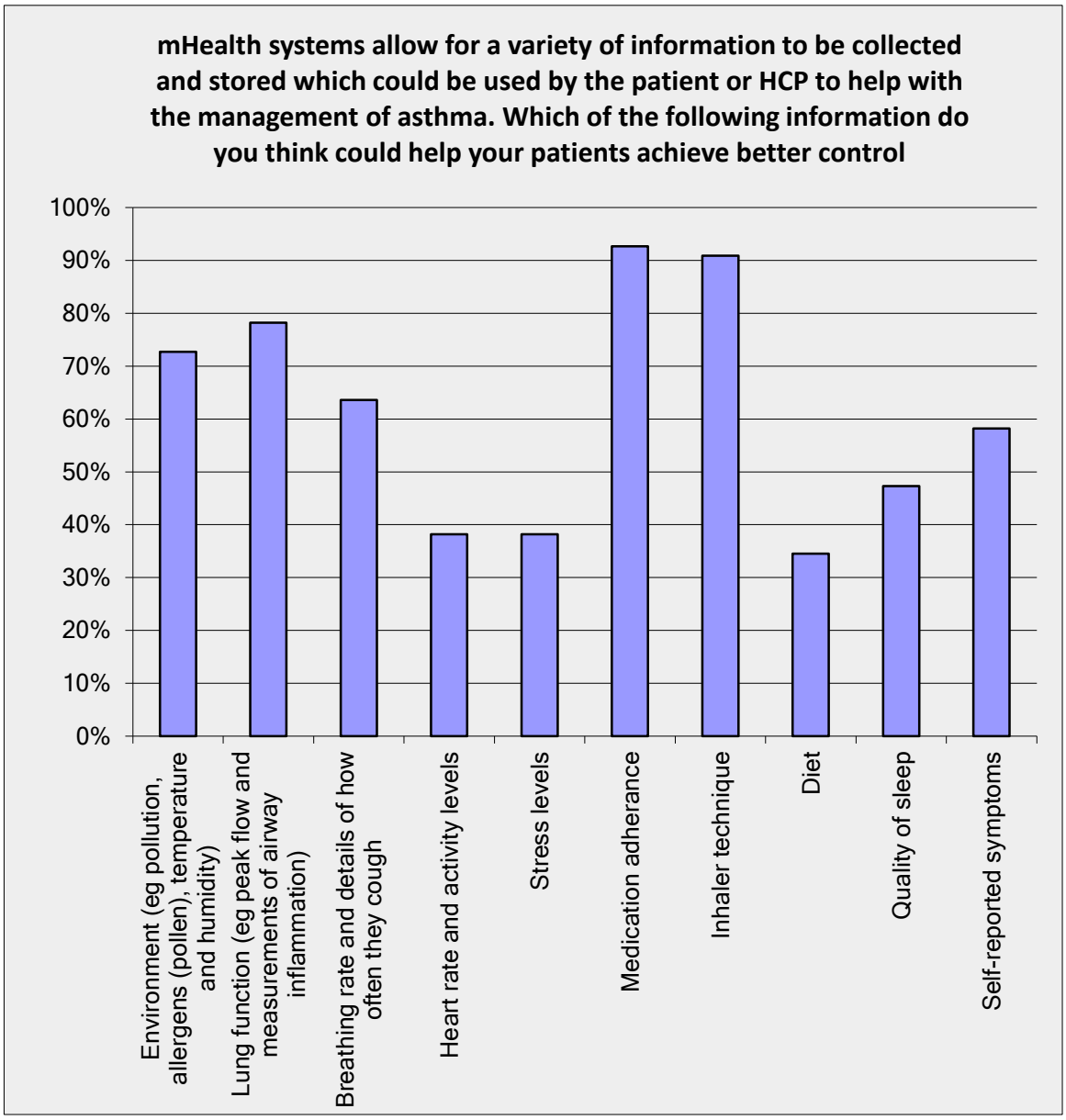


Figure 24: Information which could help achieve higher levels of asthma control

Just over 90% of HCPs felt that patients would be better at managing their asthma if the mHealth system provided information about adhering to medication and improving inhaler technique. 78% of HCPs thought it was important for patients to have information about their lung function measurements, such as peak flow and airway inflammation and 72% thought that information around their environment, such as pollution levels and allergens would improve their patients' asthma control. Fewer HCPs (35-38%) thought information about diet, stress levels and heart rate would help increase asthma control.

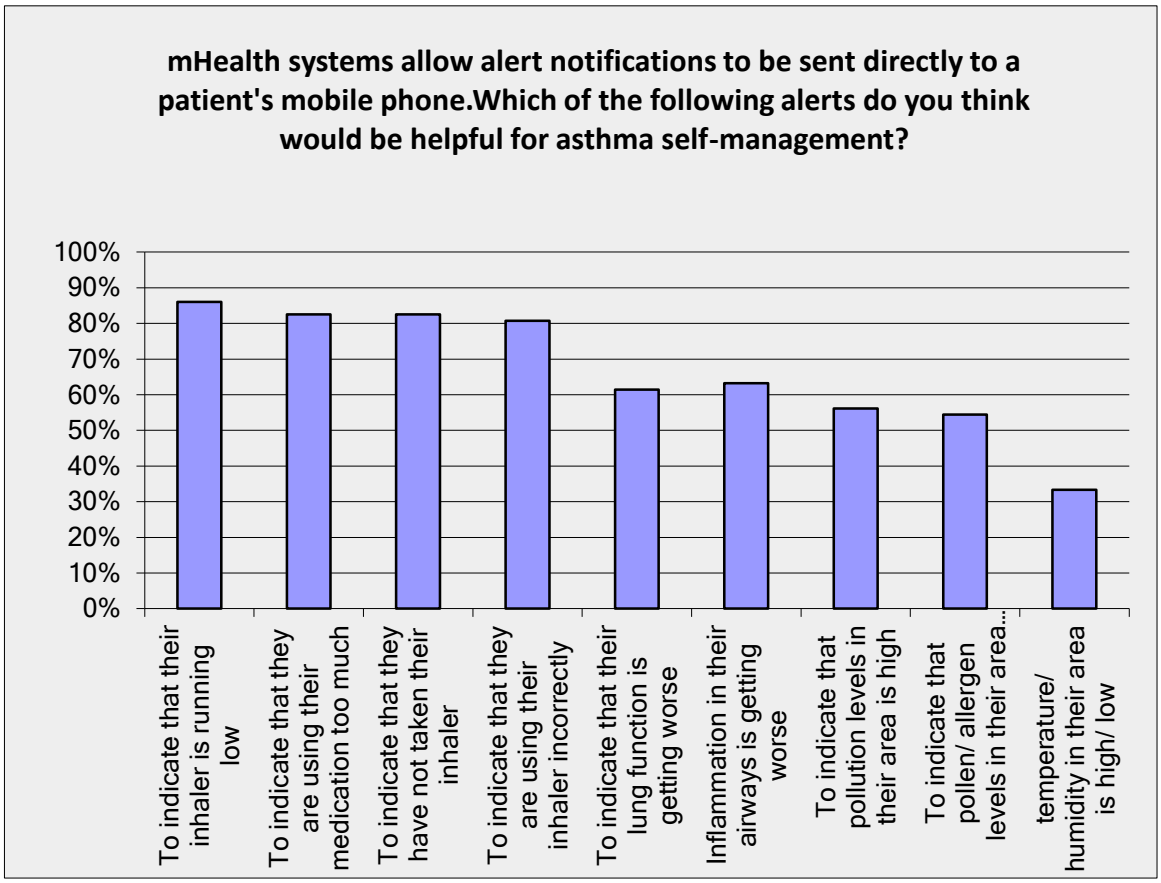


Figure 25: Alerts for patient's asthma self-management

The alerts which HCPs thought would be most helpful to people with asthma were ones to indicate their inhaler was running low, that they are using their medication too much, that they have not taken their inhaler and to indicate that they are not taking their inhaler correctly. At the other end of the scale only 33% of HCPs thought the alert for high/ low temperature and humidity in the patient's area would be helpful.

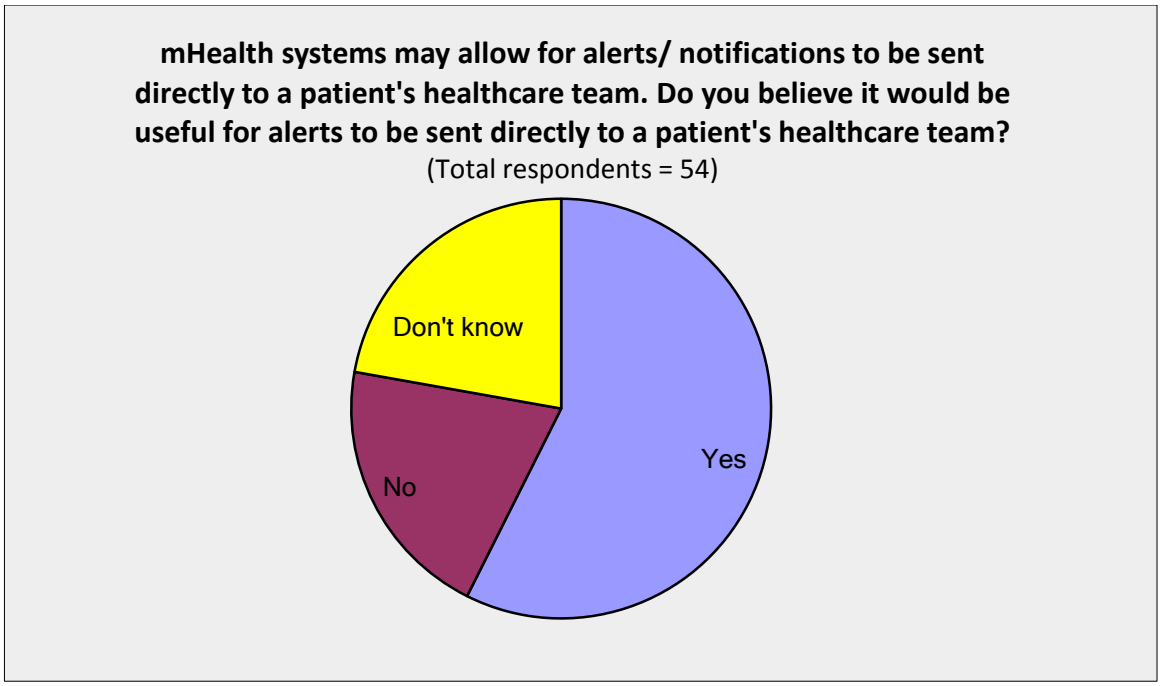


Figure 26: Usefulness of alerts sent directly to a patient's healthcare team

57% of HCPs felt it would be useful for alerts to be sent directly to a patient's healthcare team, whereas 20% thought this would not be useful. A high percentage (22%) were undecided.

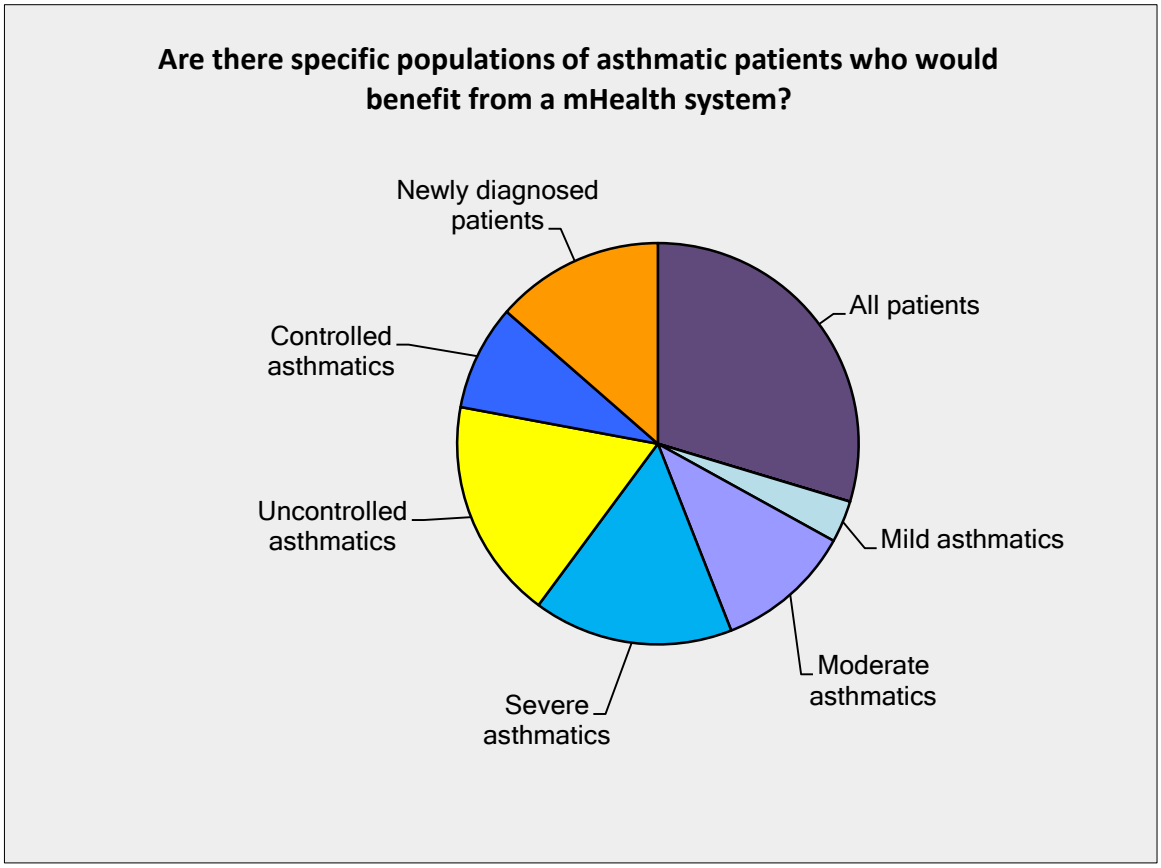


Figure 27: Populations of people with asthma who could benefit from a mHealth system

HCPs were asked who they thought would benefit from a mHealth system. 67% thought that all patients would benefit. When broken down into specific populations, most HCPs thought uncontrolled asthmatics, followed by severe and then newly diagnosed asthmatics would benefit from the system.

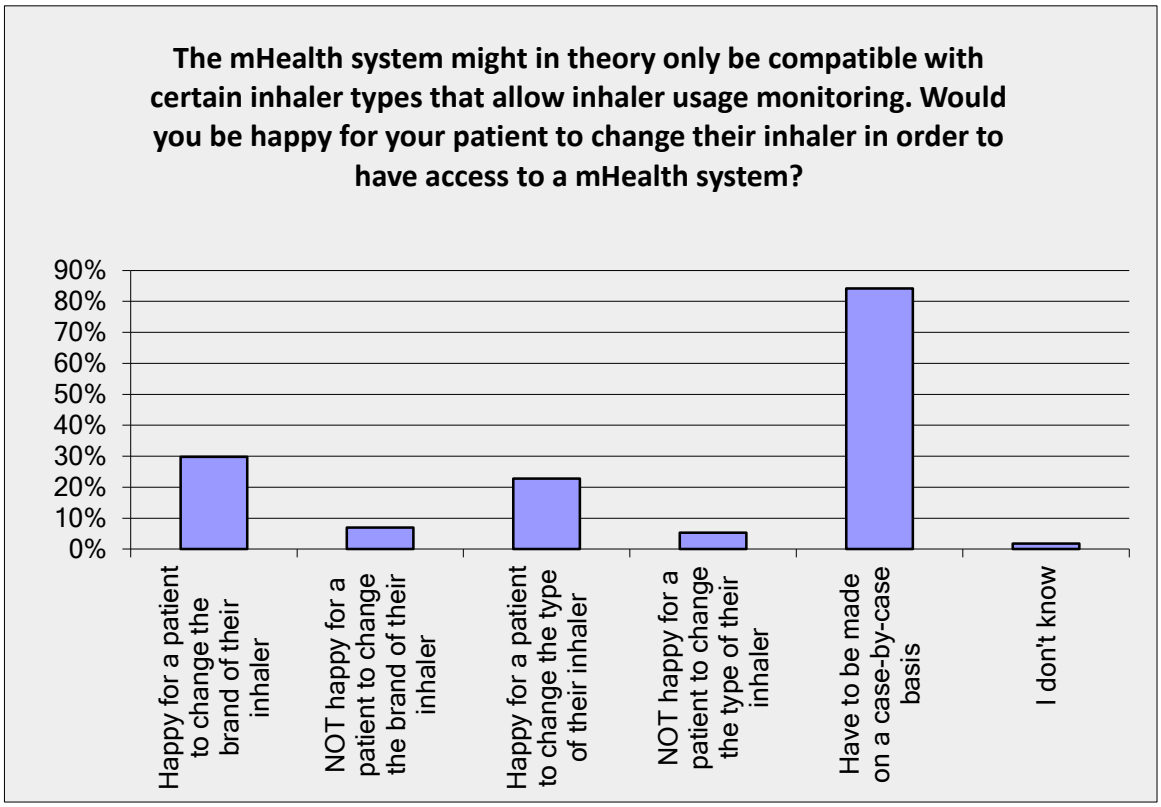


Figure 28: Acceptability of changing brand and type of inhaler

As the mHealth system may only be compatible with certain inhaler types, the HCPs were asked whether they would be happy for their patients to change their inhaler if it allowed them access to the system. The majority (84%) felt that the decision would have to be made on a case-by-case basis. Only 5% and 7% of HCPs were explicitly not happy for their patients to change the brand (drug manufacturer) and type (e.g. powder to gas) of inhaler.

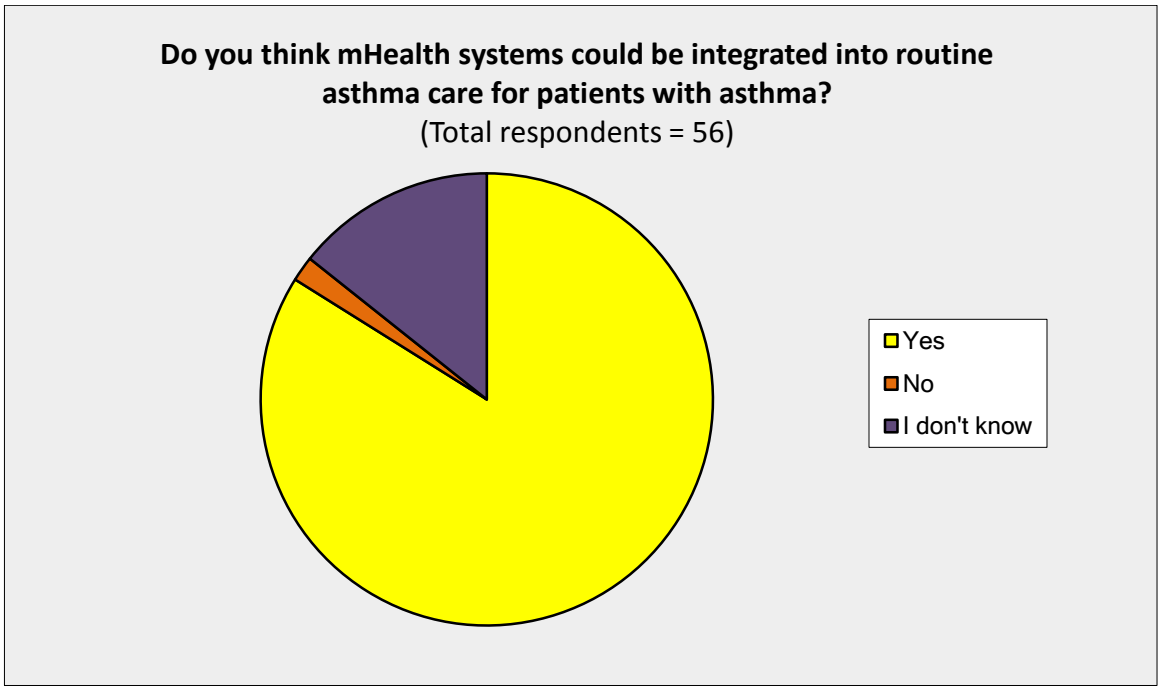


Figure 29: Integration of mHealth systems into routine asthma care

There is a strong belied that mHealth systems could be integrated into routine asthma care for patients with asthma, with 84% of HCPs agreeing with this statement. Only one HCP definitively felt that mHealth could not be integrated, and 14% were undecided.

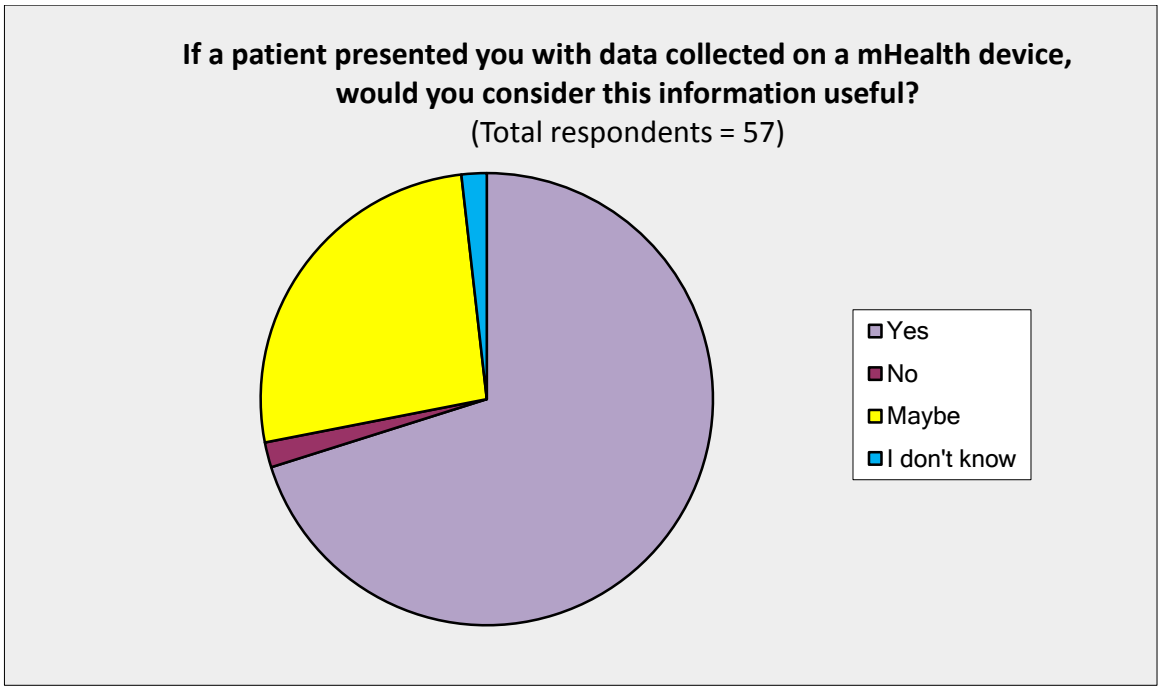


Figure 30: Usefulness of data from the mHealth system presented to the HCP

70% of HCPs thought they would find data collected on a mHealth device useful if shown by a patient. 26% thought they may find it useful and 2% thought they wouldn't or they didn't know. It was further commented that if it would increase the workload of the HCP, it would be less useful.

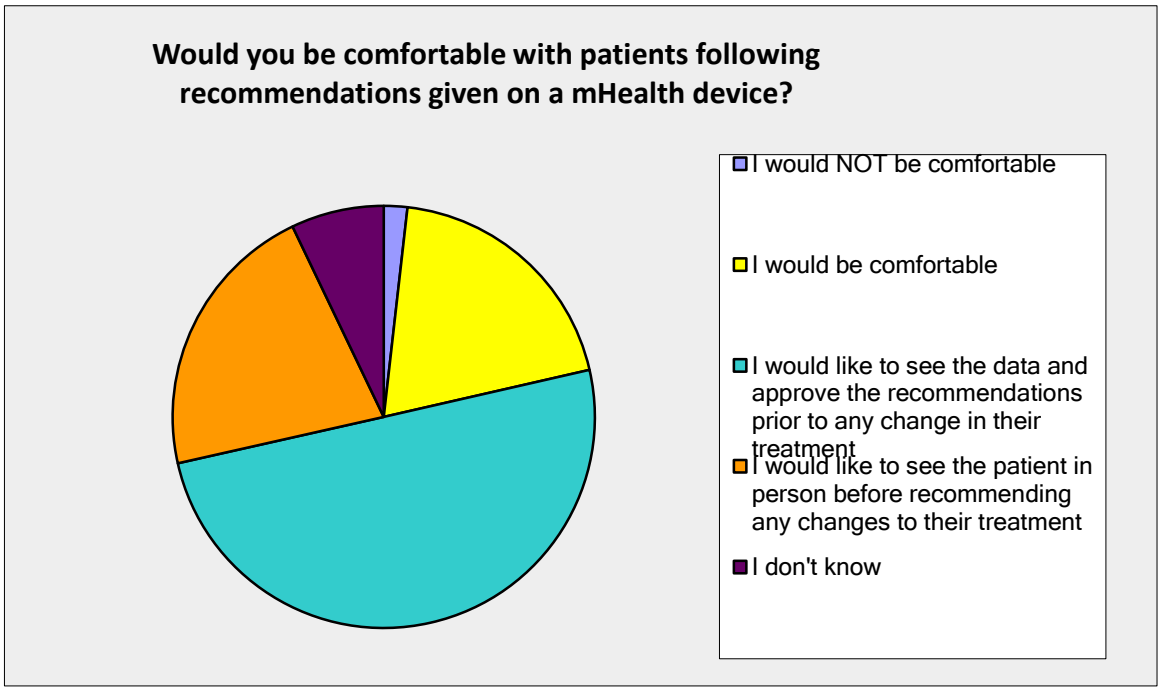


Figure 31: Acceptability of recommendations from the mHealth system

mHealth systems could provide patients with recommendations regarding their treatment based on the analysis of various measurements, in the same way as an asthma action plan. These recommendations may include the suggestion to step-up or step-down their medication or to seek medical advice. The HCPs were asked whether they would be comfortable with their patients following recommendations given on a mHealth device. 50% of HCPs wanted to see the data and approve recommendations prior to any change in treatment and 21% would want to see the patient before making any changes to treatment.

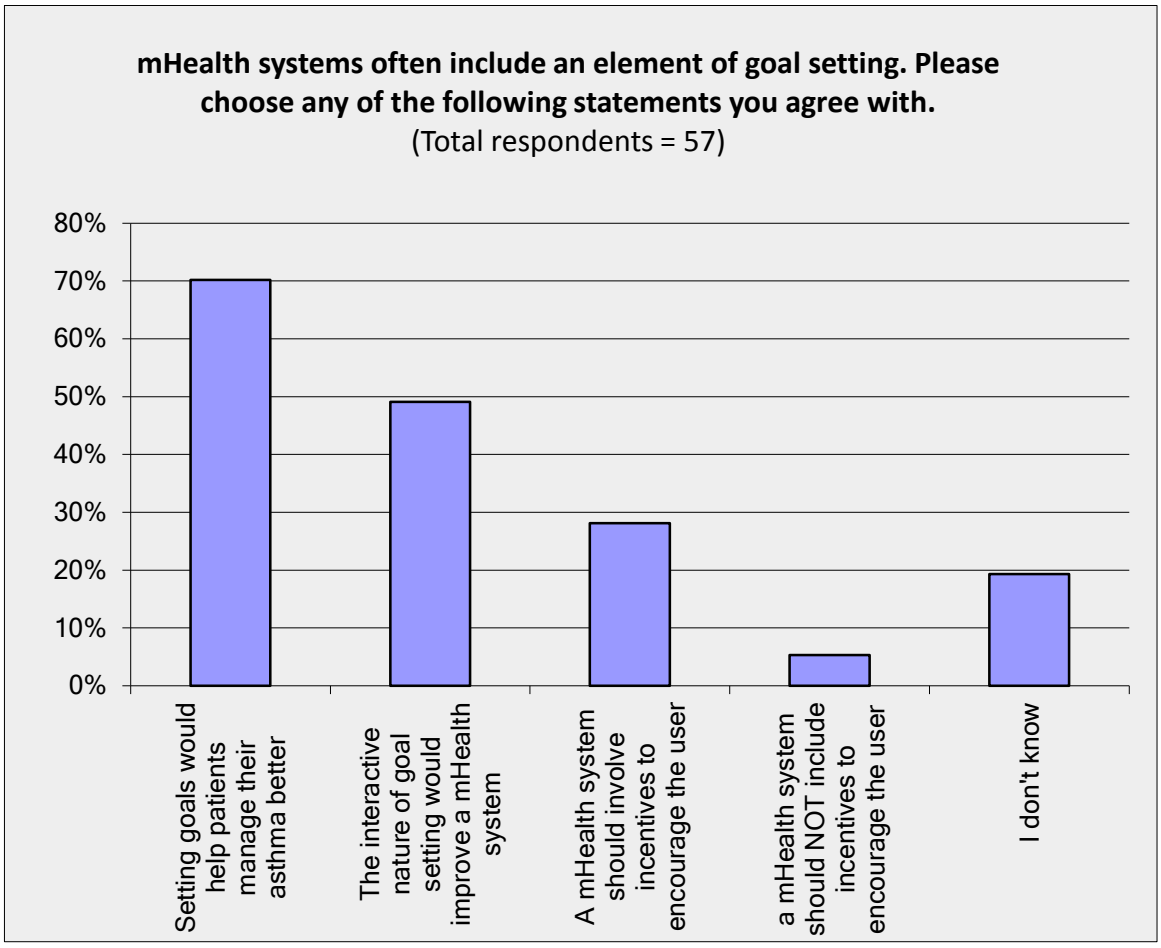


Figure 32: Usefulness of goal setting

HCPs were asked to select any statements which they agreed with in terms of goal setting. Most HCPs (70%) felt that setting goals would help patients manage their asthma better, whilst 49% thought that the interactive nature of goal setting would improve a mHealth system. No one felt that the interactive nature of goal setting would not improve a mHealth system or not help patients manage their asthma better.

3.5.3 Synthesis of results and Summary of Conclusions

Both people with asthma and the HCPs who treat them predominantly think that mHealth has a role to play in improving asthma management. Patients feel it would be particularly useful in identifying deteriorations in their condition, as well as providing them with data to show their HCP. HCPs are equally supportive of being shown a fuller

data set from their patients. Furthermore, HCPs believe that mHealth would be particularly useful in improving medication adherence and inhaler technique.

Patients who may benefit most from the system are those with uncontrolled asthma, moderate to severe asthma, and the newly diagnosed. There may additionally be benefits to targeting adolescents with asthma, as this group particularly struggles with adherence. The most popular alerts that the system could provide are the presence of triggers, a warning that an inhaler is running low, and a warning that lung function has deteriorated.

People with mild-moderate or well controlled asthma may benefit from some more basic functions, such as having their action plan on their phone, receiving reminders to take their medication, and even alerts to ensure they have their inhaler with them. This group has less motivation to invest a large amount of their time into a system when there are only limited benefits that could be realised and as such are unlikely to engage with the system in an extensive way.

People who are newly diagnosed and or have uncontrolled asthma can potentially benefit far more from the system, and in depth monitoring for a short finite time can enable them and their HCPs to learn and understand more about their individual type of asthma, what triggers it, and how best to manage it.

All participants acknowledged there is a burden associated with mHealth and the benefit of using the system has to outweigh this burden for an individual to continue using it. Patients are likely to be motivated to use the system initially but this may drop over time, and for certain patients it may be better to limit monitoring to short periods of time. On average most patients would be willing to spend up to 15 minutes per day monitoring their condition, and are willing to fill in a 2-3 minute questionnaire once a week. This will clearly vary between individual patients and those with more severe and uncontrolled asthma are more likely to spend longer engaging with mHealth. Patients are generally willing to wear one additional device although the design and appearance of this device will strongly influence an individual's propensity to wear it. Furthermore most patients would only be willing to spend up to £20 on a device.

In terms of adding sensors to existing devices, a significant subset of patients and HCPs are unwilling to change brand or type of inhaler, and a majority of patients are also unwilling to change phone type.

When considering recommendations that could be generated by the system, most patients would be happy to follow these recommendations if the system had been endorsed by the NHS. Further to this they would be more likely to follow the recommendation if a graphical representation of their data accompanied the recommendation to explain it. HCPs were more reluctant for the system to recommend changes in medications without the oversight of a HCP and were worried about the legal implications if any harm resulted following use of the system. HCPs were more happy for recommendations to advise patients to seek further medical advice, however recognised that this could result in a large increase in their workload.

The vast majority of patients are happy for their data to be shared with HCPs, although they wish to retain control over when and what is shared. They are also happy for anonymised data to be shared for research purposes.

Finally, it was clear from all the focus groups and surveys that no two people with asthma are the same; they all have different triggers, severities, co-morbidities and

health beliefs, all of which influence the presentation of their condition and how they manage it. A successful mHealth system therefore must be customisable to every individual and this could be achieved by offering a wide range of monitoring options from which the individual and their HCP select the most appropriate three or four options to use.

On the basis of the combined approach detailed above, we have identified the following user priorities that we believe the MyAirCoach project can address:

1. Better use of action plans by provision of an action plan on a mobile phone
2. Improvements in inhaler technique
3. Monitoring of medication usage and adherence
4. Alerting patients to when their individual triggers may be present
5. Improved understanding of an individual's asthma
6. Prediction or earlier identification of exacerbations, enabling earlier treatment
7. Sharing of anonymised data to aid research
8. Data collection for clinical trials
9. Better definition of asthma phenotypes
10. Increased interactions between HCPs
11. Enable remote feedback from HCPs to patients
12. Identification of side effects of medication

4 MyAirCoach Use Case Scenarios and Evaluation Protocols

This section defines the MyAirCoach use cases based on the user requirements, the defined specific goals of the project as they will be available using the above methodology and procedures.

4.1 MyAirCoach Provisional Use Case scenarios

Two use case scenarios have already been described in the Description of Action (DoA) and they will be the basis for the development of the application scenarios (within WP6) that will serve the evaluation of the MyAirCoach developments. For simplicity, these original use cases are given below, while a template of application driven use cases is provided in detail in the subsequent sections:

4.1.1 Automated sensing and self-management of asthma.

Patient who has been hospitalised for asthma in the previous year has been educated in self-management supported by the MyAirCoach system and can now actively participate in his treatment. Based on a shared-decision making approach and his self-management and asthma profile the patient knows how to adjust treatment according to an individualised action plan that specifies when and how to adjust treatment (step-up and step-down instructions), for how long and when to seek medical help. The novel sensor-equipped inhaler checks his inhalation technique, which is crucial for really effective treatment. When a critical step is omitted the patient gets an instant message that corrects his omission. In addition, the inhaler registers when and where the patient uses his medication and the system sends gentle reminders when the patient has forgotten to take the medication within a pre-specified timeframe. Typically, this patient with asthma is sensitive to certain (inhaled) stimuli like (grass) pollen and/or changes in weather and air pollution. Therefore, the MyAirCoach system provides a forecast for relevant pollen and/or sends alerts when the pollen concentration and/or air pollution reaches critical values in his environment. Indeed, by getting this message he realises that his symptoms are already getting worse. Because the patient feels reassured he adjusts his medication and behaviour in order to avoid exposure as much as possible and prevent the development of a full-blown exacerbation. He only suffers from mild symptoms this time. However, when his symptoms are well-controlled he remembers that a year ago he used to stop taking his controller medication in such a situation. Now the MyAirCoach system provides a personalised advice to step-down his medication after a few days when symptoms are well-controlled. He now experienced that a low dose of controller medication keeps his asthma well-controlled for most of the time and enables him to participate in his social activities. The MyAirCoach system supports his self-management with timely alerts and reminders.

4.1.2 Prediction and estimation of worsening asthma control.

There is enormous current interest in the development of strategies, which may improve respiratory disease control and decrease disease exacerbations in patients with asthma and COPD. However, particularly in asthma, which is a disease of airway response variability depending on the environment, disease control goes through periods of stability (controlled) and instability (uncontrolled), and often these periods of instability occur when the patient is at home away from the hospital setting, and are difficult to capture. Identifying those patients with poor asthma control and the predictors of poor asthma control is critically important; especially to allow a group that

may be targeted for focused drug treatment intervention. Hence, asthma patient cohorts in clinical trials (which tend to be a mixed group of stable and relatively unstable asthma patients at any one time) have to be followed up for prolonged periods if false negative drug studies (with respect to asthma control and disease exacerbations) are to be avoided. This in turn means that drug trials may be prohibitively expensive, and results delayed. An important advance of MyAirCoach would be to be able to develop the framework that would allow near-point testing of the patient at home in order to assess new respiratory medical strategies in settings that are being developed specifically to improve asthma control and improve disease exacerbations. Also, what about the patients who are not optimally taking their inhaled anti-inflammatory treatment? In this group, an expensive new inhaled therapy would not be the right next step in management. Indeed, instead, improving inhaler treatment compliance would be the important step.

The patient models and clinical prediction framework of MyAirCoach will allow medical staff to assess and predict the poor asthma control on a case-by-case basis, based on the input of the physiological, environmental and behavioural information provided by the MyAirCoach sensing infrastructure. This will allow the selection patients that have poor asthma control. Such patients will form a unique group that may manifest treatment dependent improvement in disease control, leading to lower drug development costs and lessening of the risk of a false negative study. Moreover, once a new medical treatment strategy becomes available, MyAirCoach will allow the identification of those patients with poorer asthma control that stand to benefit more from that treatment. Such stratification of patients for treatment based on the aggressiveness of the disease process is a cornerstone of therapy with disease modifying agents in conditions where such therapies already exist, such as in other respiratory conditions.

4.2 Application driven use cases

In this section, we present the application driven use cases for the MyAirCoach platform. We first provide a description of the actors (or user roles) that will interact with the system; we then describe the functionalities each wants to access as perceived by the MyAirCoach actors.

4.2.1 Actors

The MyAirCoach system and more specifically the graphical user interface of the MyAirCoach Analytics tools will be the main interface between the MyAirCoach tools and the involved actors. The identified actors (based on the identified targeted user groups analysed in section 3.2) are:

1. The Patient
2. The Patient's family
3. The Clinician/ medical professional actor
4. The Researcher/expert actor
5. The Community of asthma patients

4.2.2 Use Cases

In this section, the main application-driven use cases of the MyAirCoach platform Framework are described. The use cases are based on the findings of WP1 efforts and they are further elaborated in this report focusing on the dynamic behaviour of the system. For the analysis of the use cases, an initial template for gathering the Use Cases has been elaborated in this report, as illustrated in the following table:

Table 3: Template for the analysis of the MyAirCoach system through high-level use cases

Use Cases Template for drafting the detailed specifications of the MyAirCoach system architectural elements	
Generic Description	
Use Case Name	*In this section enter a Use Case name, which uniquely identifies the UC (e.g. unique identifier), having an achievable goal*
Version	*To inform the user the stage a use case has reached.*
Authors	*Who created and who documented the Use Case*
Last Update	*Shall include all previous updates made to the actual Use Case.*
Brief Description	*Please describe the series of steps for the defined use case in a clear concise manner. Include in the description what the MyAirCoach system shall do for the involved actor to achieve a particular goal.*
Assumptions & Pre-	*This part may describe the conditions that generally does not*

Conditions	*change during the execution and should be true to successfully terminate the use case.* *Moreover, pre-conditions define all the conditions that must be met (i.e., it describes the state of the system) for the meaningfully cause the initiation of the use case.*
Goal (Successful End Condition)	*The ultimate aim and end condition(-s) of the Use Case*
Post-Conditions	*The effects of this UC to the overall state of the system or of its core architectural elements.*
Involved Actors	*Who are the actors involved in the use case? The same actor may play two different roles in the same use case.* *An actor may be a person, a device, another system or sub-system, or time. Actors represent different roles that something outside has in its relationship with the system, functional requirements of which are being specified.*
Use Case Initiation	*This refers to the potential triggers or events that could initiate the use case. The type of trigger can be temporal, internal or even in respond to an external event. Normally, the initiation of a UC shall take into account also the pre-conditions, e.g. checking them prior the execution of the UC.*
Main Flow	*This section shall describe the typical course of events that comply with the primary scenario addressed by the UC. Basic course of events could be enough using a step-based approach.*
Relationships with other Use Cases	*Indicates connection with other use cases*
Specific Description	
Relevance to MyAirCoach WPs	*Please report the relevance to the MyAirCoach WPs*
Privacy & Regulation restrictions	*Refer to any concerns on this perspective during the execution of the use case*
Environmental restrictions	*Refer to any concerns on environmental restrictions during the execution of the use case*
Quality of service indicators	*Please refer to indicators regarding the performance, and scalability of the involved architectural elements in this UC.*
References (optional)	*Any reference to other reports or material helpful for the reader*
Notes (optional)	

UML Sequence Diagram	*Provide through a sequence diagram the logic of a complex operation, function or procedure that is implied by the use case. It contains the key architectural elements and outlines the main execution flow during the instantiation of this use case.*

4.2.2.1 Exclusively patient oriented use cases

The current section includes the use cases that where the patient is the main user. It is important to underline that all use cases of the project will be aiming to achieve empowerment of patients and the optimum management of their disease and therefore they can all be characterised as patient oriented.

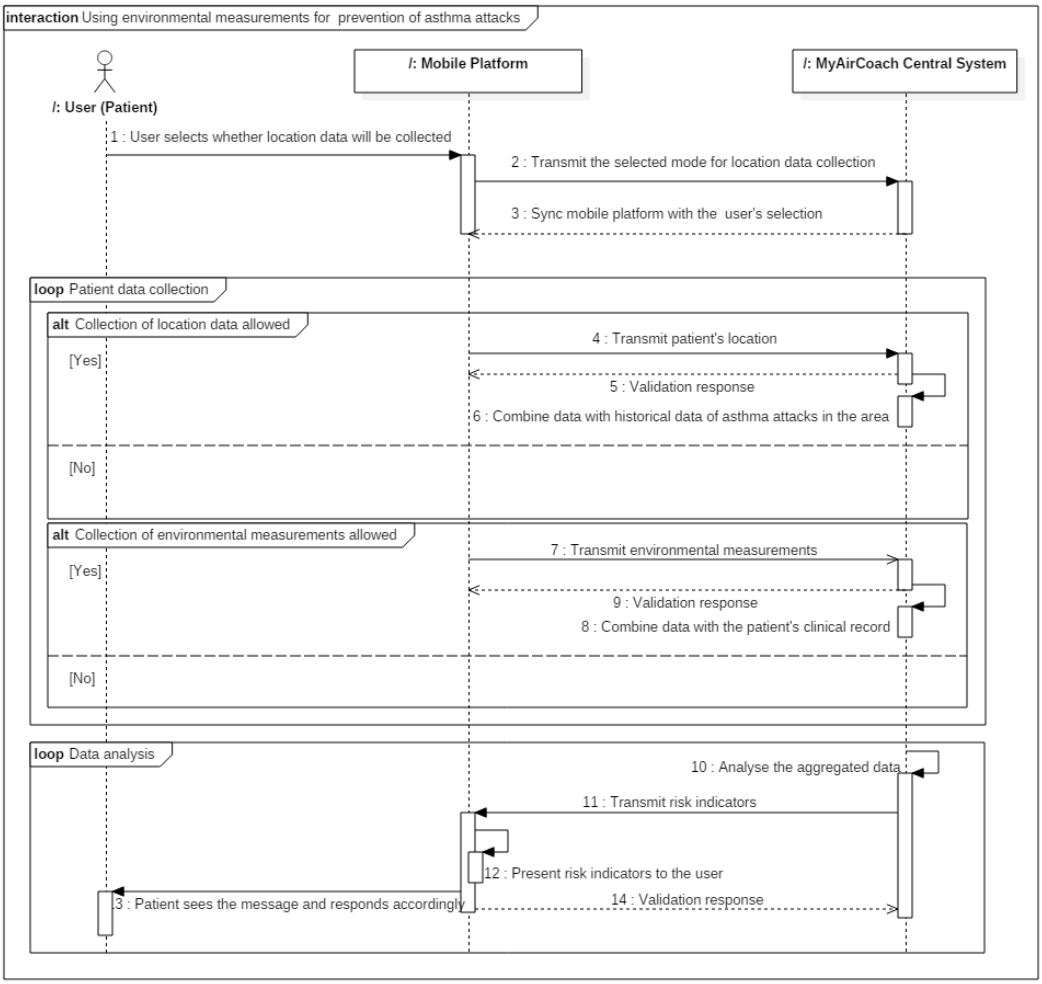
UC1.1 – Using the environment measurements for the prevention of asthma attacks

Generic Description	
Use Case Name	*UC1.1 – Using environmental measurements for the protection/information of the user.*
Version	*V1.0*
Authors	*CERTH-Allertec*
Last Update	*December 2015*
Brief Description	*The user enters an area of high pollution or high concentration of an allergen. The myAirCoach system collects all the measurements of the myAirCoach sensing module and combines them with historical medical data of the patient. An alert appears on the smartphone suggesting that she/he should move away. When the patient chooses to stay information is provided regarding the medication to be used in the case of asthma attack, based on the asthma action plan of the patient.*
Assumptions & Pre-Conditions	- *The MyAirCoach architecture components should be successfully integrated.* - *The MyAirCoach Analytics component should be capable of loading measurements and combine them with historical data for the specific patient and the history of asthma attacks in the specific area.* - *The MyAirCoach system should be installed to the user's smart device.* - *The implemented MyAirCoach GUI provides all the necessary interfaces for the presentation to the user of personalised alerts and instructions.* - *The myAirCoach system is capable of allowing personalised parameters of an asthma action plan to be set*

Goal (Successful End Condition)	- *The patient is informed in a timely manner for the possible dangers in her/his environment.* - *The patient is presented with personalised and localised instructions that reduce the risk of exacerbation.*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	*Patient.*
Use Case Initiation	*This Use Case is initiated after the patient enters an area of high exacerbation risk.*
Main Flow	1. *The user allows the collection of multisensorial data (e.g. location).* 2. *The user preferences are transmitted from the mobile platform of the user to the MyAirCoach central DSS system.* 3. *The user enters an area of high risk of exacerbations.* 4. *The environmental sensor measurements are sent to the central system while web information from meteorological data are also provided to the system.* 5. *The measurements are combined with the clinical record of the corresponding patient.* 6. *The measurements are combined with the historical data of exacerbations in the specific area (coming also from other patients/users).* 7. *The aggregated data are analysed and specific prediction risks and factors are calculated.* 8. *The MyAirCoach GUI informs the patient about the related risks.* 9. *The MyAirCoach GUI informs the patient about the optimal medication to use in order to minimise all safety risks and prevent exacerbations.*
Relationships with other Use Cases	*UC1.5*
Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP3, WP4, WP5*
Privacy & Regulation restrictions	*The loaded patient data should not be stored to any local databases or transmitted outside the framework of the central MyAirCoach system.*
Environmental restrictions	*The patients environmental conditions should be accessible by the system (MyAirCoach sensing components, commercial devices, online resources)*

Quality of service indicators	*Notification of the patient regarding risk factors in her/his environment. Preservation of the patient's safety through the optimisation of the suggested medication.*
References (optional)	*No references are noted.*
Notes (optional)	*No additional notes*

UML Sequence Diagram

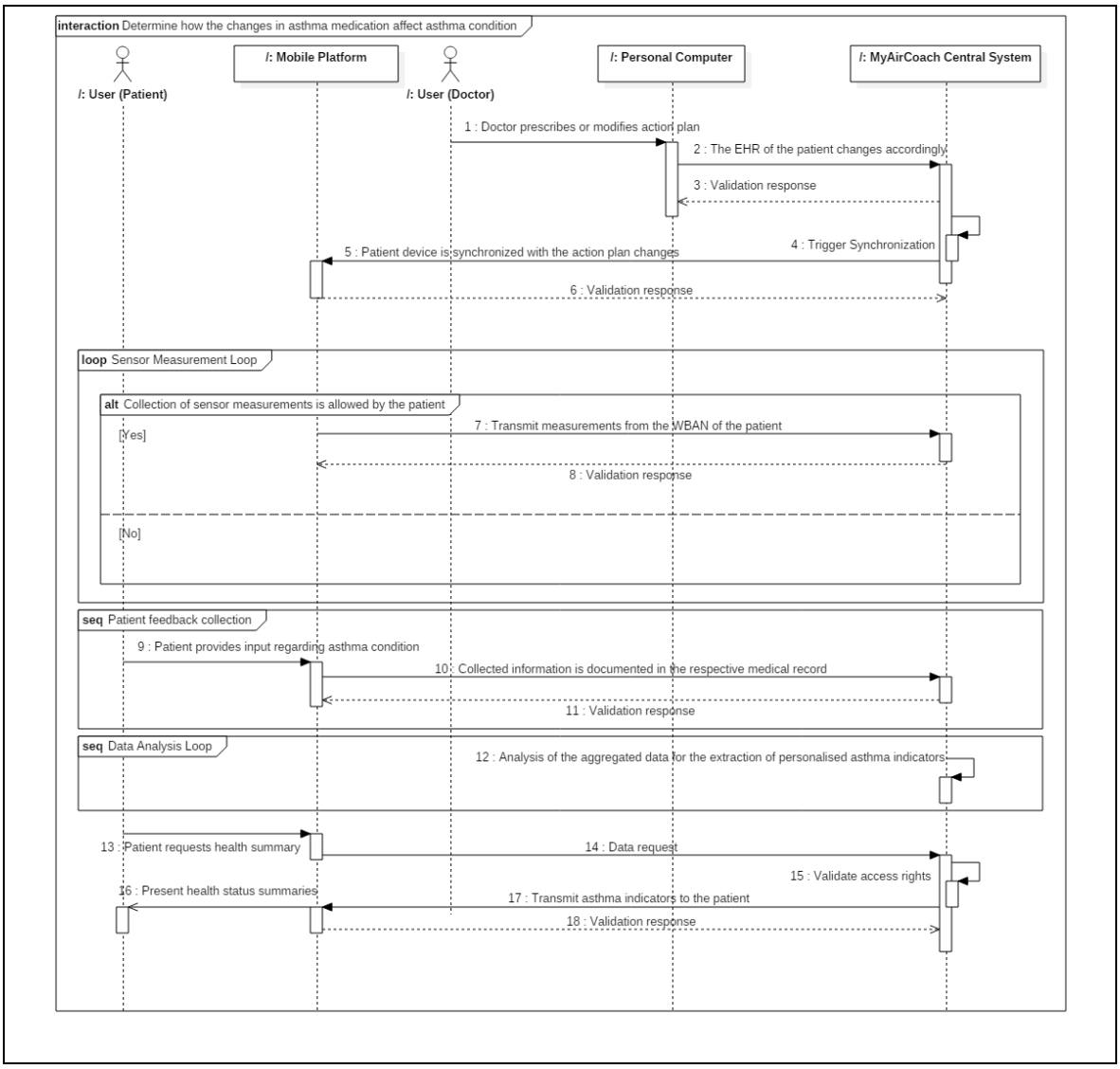


UC1.2 – Using the MyAirCoach system to determine whether stepping up the current therapy or changing asthma medication improves asthma control

Generic Description	
Use Case Name	*UC1.2 - Using the myAirCoach system to determine whether stepping up the current therapy or changing asthma medication improves asthma control*
Version	*V1.0*

Authors	*ICL*
Last Update	*December 2015*
Brief Description	*A patient could use the myAirCoach system to assess how the recommendation received by the GP or the specialist to increase the dose of his/her current therapy, to add a new drug or to move to a new treatment strategy impacts his/her asthma control and quality of life. The patient could achieve this by recording a wide panel of functional and inflammatory asthma markers and by accessing an electronic diary to monitor trends in symptoms, lung function, use of rescue medication, etc.*
Assumptions & Pre-Conditions	- *The myAirCoach architecture components are successfully integrated.* - *The myAirCoach components are capable of recording functional and clinical parameters, as well as combining them with historical patient's data* - *The myAirCoach analytics components are able to extract asthma indicators from the medical record of the patient (clinical exams and sensor measurements)* - *The myAirCoach system provides all the necessary interfaces for the presentation of data to the user through informative visualisations that require minimal knowledge about the asthma pathophysiology.*
Goal (Successful End Condition)	- *The patient is actively involved in his/her asthma management and understands the importance of all the components of the prescribed action plan* - *The patient improves his/her compliance to medication* - *The patient understands the importance of accurate input to GP and provides additional information to the collected data.*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	- *Patients* - *Healthcare professionals*
Use Case Initiation	*This use case initiates after healthcare professionals prescribes or modifies the patient's treatment*
Main Flow	1. *The GP prescribes or modifies the medication action plan of a patient* 2. *The patient uses the myAirCoach system to document clinical, functional and inflammatory parameters of his/her asthma condition* 3. *The myAirCoach system records important asthma parameters with corresponding time stamp and within the everyday activities of the patient.* 4. *All data are automatically transferred to a secure database* 5. *The MyAirCoach system uses the collected data in order to*

	calculate informative personalised indicators of asthma disease *6. The MyAirCoach system creates personalised informative and easy to understand summaries of the patients medical record that can be used by patients irrespective of their educational background.* *7. The patient is able to access his/her personal data with a suitable interface for determining asthma trends*
Relationships with other Use Cases	*UC 3.3*
Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP3, WP4, WP5*
Privacy & Regulation restrictions	*The loaded patient data should not be stored to any local databases or transmitted outside the framework of the central myAirCoach system.*
Environmental restrictions	*No environmental restrictions.*
Quality of service indicators	*The patient is personally able to determine the effectiveness of modified or new treatments*
References (optional)	- *None*
Notes (optional)	- *None*
UML Sequence Diagram	

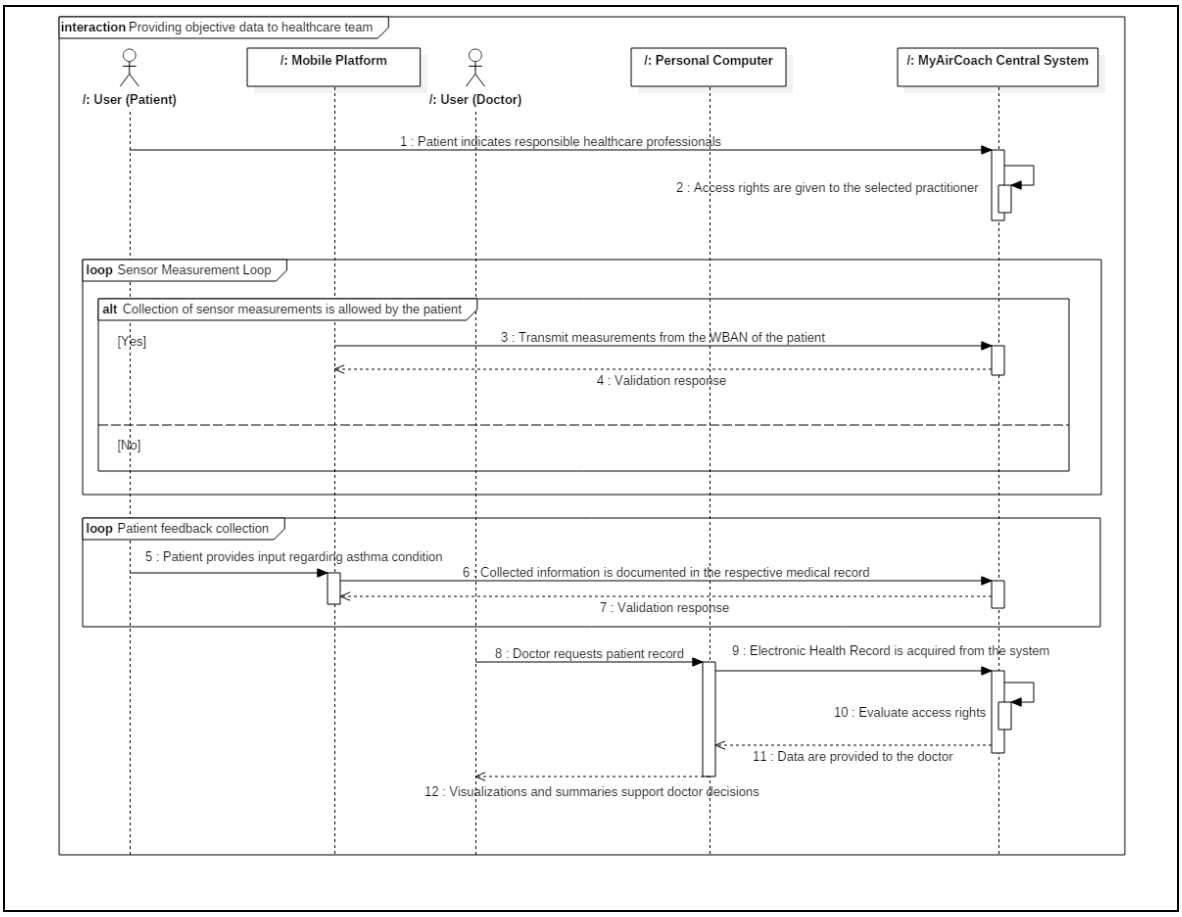


UC1.3 – Monitoring of asthma by patients to provide objective evidence of their condition to their healthcare team

Generic Description	
Use Case Name	*UC1.3 Monitoring of asthma by patients to provide objective evidence of their condition to their healthcare team*
Version	*V1.0*
Authors	*UMAN*
Last Update	*December 2015*
Brief Description	*A patient could use the myAirCoach system to demonstrate the state of their asthma to their healthcare team. The myAirCoach system could record asthma symptoms and other indicators of asthma state (i.e., lung function and medication usage) for patients to discuss with their healthcare team at medical visits. By recording asthma symptoms and clinically relevant data, participants could provide their healthcare team with*

	documented, objective, evidence of their asthma state in the days, weeks or months preceding their healthcare visit. ***Note**: This use case was developed following the patient focus groups. Indeed, at the focus groups patients highlighted that they often find it hard to communicate their recent asthma state with their healthcare team. The variable nature of the condition often means that at the time of a healthcare appointment, patients' asthma may not be reflected of their recent state. At these focus groups, patients proposed that a system capable of documenting their asthma state prior to a healthcare visit would be useful when attending medical appointments.*
Assumptions & Pre-Conditions	- *The myAirCoach system is capable of collecting clinically relevant data (e.g., asthma symptoms, lung function data etc.)* - *The myAirCoach system is capable of recoding the time and date of data input* - *The myAirCoach system is capable of transferring data to a secure database* - *Healthcare professionals are able to access patient's data when they attend their medical appointment*
Goal (Successful End Condition)	- *The healthcare professional is able to access and utilise data collected by the myAirCoach system to better understand the current state of their patient's asthma*
Post-Conditions	- *The system maintains its stability and it is able to respond to new inputs*
Involved Actors	- *Patients* - *Healthcare professionals*
Use Case Initiation	- *A patient starts collecting and storing all relevant data* - *The patient then attends their medical appointment*
Main Flow	1. *A patient uses the myAirCoach system to collect symptoms and clinical relevant data regarding their asthma (Use of both sensors and questionnaires)* 2. *Doctors and healthcare professionals are able to include their inputs to the Electronic Health Record of the patient (Diagnosis, Comments, Medication, Action plans)* 3. *Data are automatically transferred (backed-up) to a secure database* 4. *The myAirCoach data representation scheme can support all the required types of information within a secure framework* 5. *The healthcare team is able to access the data whenever required (e.g. Doctor visits, Emergency situation)* 6. *The data is provided with a suitable interface for determining data trends and help doctors understand the important*

	parameters related to the patient's asthma condition
Relationships with other Use Cases	
Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP3, WP4, WP5*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local databases or transmitted outside the framework of the central myAirCoach system* - *Only the responsible health care professionals should have access to the patient's record (As indicated by the patient)*
Environmental restrictions	- *None*
Quality of service indicators	- *Improves the ability for patients to communicate their current asthma state with their healthcare time* - *Healthcare professionals are able to access patients data for discussion with the patient at their clinic appointment*
References (optional)	- *None*
Notes (optional)	- *None*
UML Sequence Diagram	



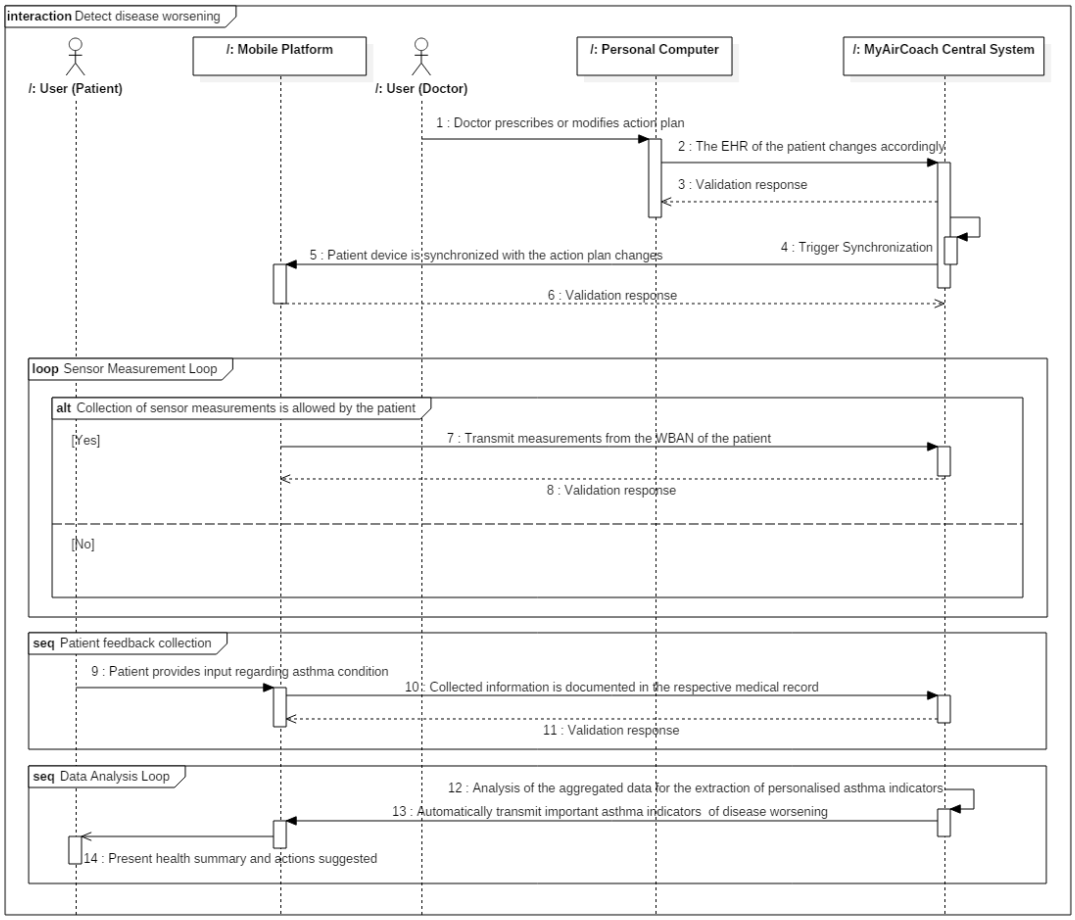
UC1.4 – Using the MyAirCoach system to monitor asthma control and detect disease worsening

Generic Description	
Use Case Name	*UC1.4 Using the myAirCoach system to monitor asthma control and detect disease worsening*
Version	*V1.0*
Authors	*ICL*
Last Update	*December 2015*
Brief Description	*A patient could use the myAirCoach system to personally monitor his/her asthma control and early detect signs of disease deterioration, as well as risk factors for the occurrence of exacerbations. This could be achieved thanks to the information provided by the myAirCoach system on the basis of physiological, environmental and behavioural parameters. This would help the patient to notice asthma worsening before they would normally notice through onset or worsening of symptoms*
Assumptions & Pre-Conditions	- *The myAirCoach architecture components are successfully integrated.* - *The myAirCoach components are capable of recording clinical, functional and inflammatory parameters, as well as*

	combining them with historical patient's data - *The myAirCoach system provides all the necessary interfaces for the presentation of data to the user* - *The myAirCoach system provides alerts to the patient to warn him/her about asthma deterioration* - *The myAirCoach system suggests actions to be taken*
Goal (Successful End Condition)	- *Patient warned about asthma deterioration in a timely manner*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs*
Involved Actors	- *Patients*
Use Case Initiation	*This Use Case initiates when parameters collected through the MyAirCoach system suggest asthma worsening*
Main Flow	1. *The MyAirCoach system collects physiological, environmental and behavioural data related to the asthma condition of the patient* 2. *Data are automatically transferred to a secure database* 3. *The measurements are combined with the historical records of the patient.* 4. *The aggregated data are analysed and risks are predicted* 5. *The patient is able to access his/her personal data with a suitable interface for visualising data trends* 6. *The MyAirCoach GUI informs the patient about the current health status and related risks* 7. *The MyAirCoach GUI suggests to the patient the most appropriate actions to be taken in order to restore asthma control and prevent exacerbations.*
Relationships with other Use Cases	*UC1.5*
Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP2, WP3, WP4, WP5*
Privacy & Regulation restrictions	*Patient data should not be copied and/or stored in any local database and transmitted outside the network of the myAirCoach system*
Environmental restrictions	*None*
Quality of service indicators	- *Improved asthma control* - *Reduction of exacerbations* - *Reduction of hospitalisations*

References (optional)	*None*
Notes (optional)	*None*

UML Sequence Diagram

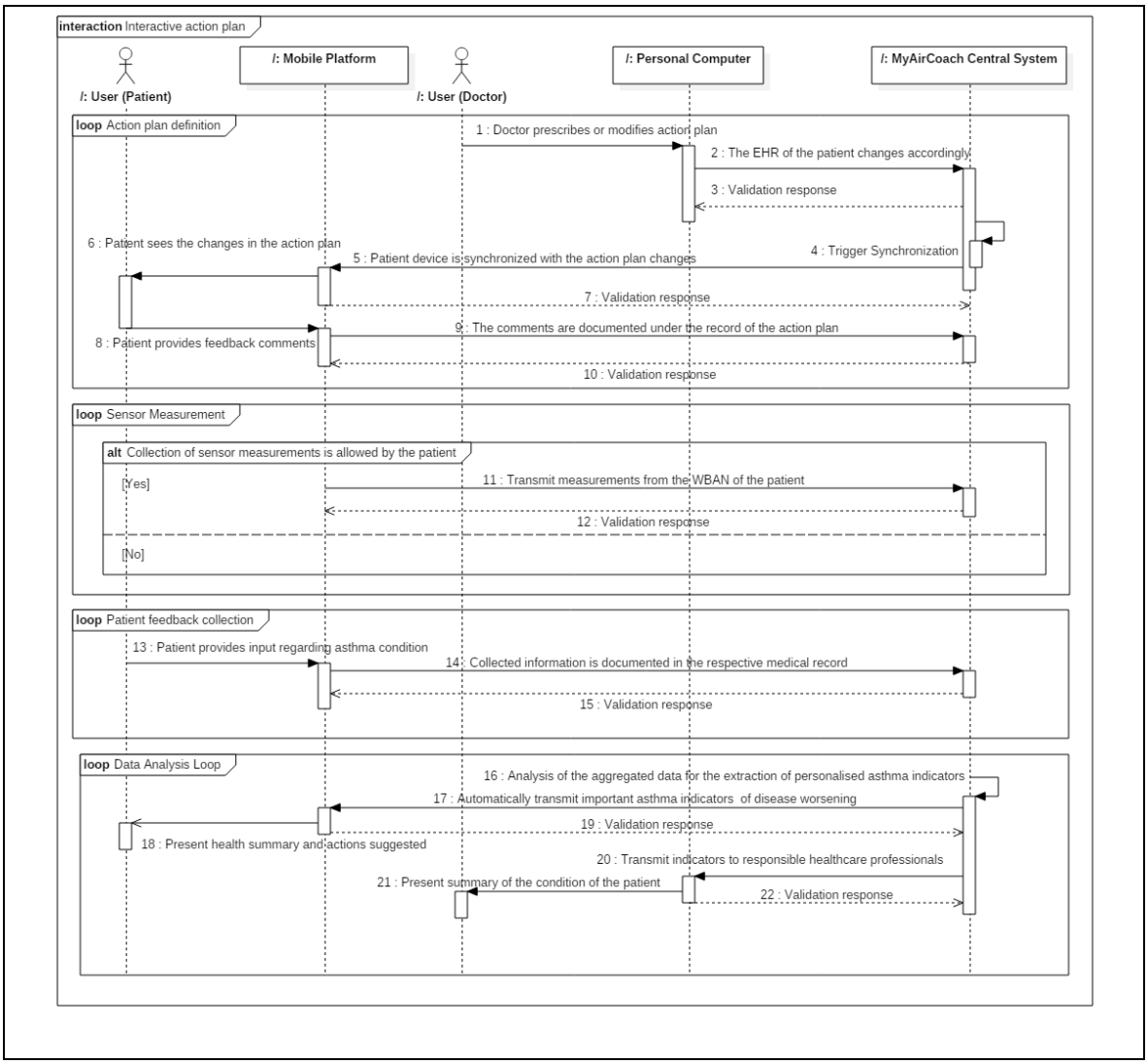


UC15 – The use of the MyAirCoach system as an electronic version of a patient's action plan

Generic Description	
Use Case Name	*UC.1.5 The use of the myAirCoach system as an electronic version of a patient's asthma action plan*
Version	*V1.0*
Authors	*UMAN*
Last Update	*December 2015*
Brief Description	*Patients are often given personalised asthma action plans by their healthcare teams. These action plans contain simple algorithms, usually written on paper or in paper workbooks, which advise a patient on what they should do if they detect changes in their asthma symptoms and/or physiological*

	measurements (i.e., lung function). Despite the recognised benefits of asthma action plans, patients rarely use them. An electronic device may improve adherence to these action plans and the myAirCoach system will provide an ideal platform for this. *A patient and doctor can devise an action plan together and input the parameters of the action plan into the myAirCoach system. The patient can record their symptoms and physiological data using the myAirCoach system. When a parameter of their asthma action plan is violated the myAirCoach system can alert the patient by providing them with instructions regarding the actions they should.* ***Note**. This use case was developed following the focus group discussions with patients.*
Assumptions & Pre-Conditions	– *The myAirCoach system is capable of allowing personalised parameters of an asthma action plan to be set* – *The myAirCoach system is capable of collecting relevant data (i.e., asthma symptoms and lung function data)* – *The myAirCoach system is capable of detecting when a parameter of the action plan is violated* – *The myAirCoach system is able to send a prompt with instructions to the patients with regards to their proposed action* – *The myAirCoach system allows the notification of the responsible doctor regarding situations of high risk for the patient.*
Goal (Successful End Condition)	– *A patient uses the myAirCoach system as their asthma action plan and automatically receives notifications and instructions when their asthma requires action*
Post-Conditions	– *The system maintains its stability and it is able to respond to new inputs*
Involved Actors	- *Patients* - *Healthcare professionals*
Use Case Initiation	– *Patient and doctor input asthma action plan parameters*
Main Flow	1. *A healthcare professional and their patient configures the parameters of the asthma action plan on the myAirCoach system* 2. *A patient uses the myAirCoach system to regularly record relevant data (e.g., lung function, asthma symptoms etc.)* 3. *A change in a patient's asthma that violates a parameter of their asthma action plan is detected by the myAirCoach system*

	4. Patient receives the alert and instructions on how to manage their asthma
Relationships with other Use Cases	*UC1.1, UC1.4*
Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP3, WP4, WP5*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local databases or transmitted outside the framework of the central myAirCoach system* - *Only prescribing healthcare professionals can set the parameters of an asthma action plan*
Environmental restrictions	- *None*
Quality of service indicators	- *myAirCoach system allows for personalised asthma action plans to be set and followed by a patient*
References (optional)	- *None*
Notes (optional)	- *None*
UML Sequence Diagram	



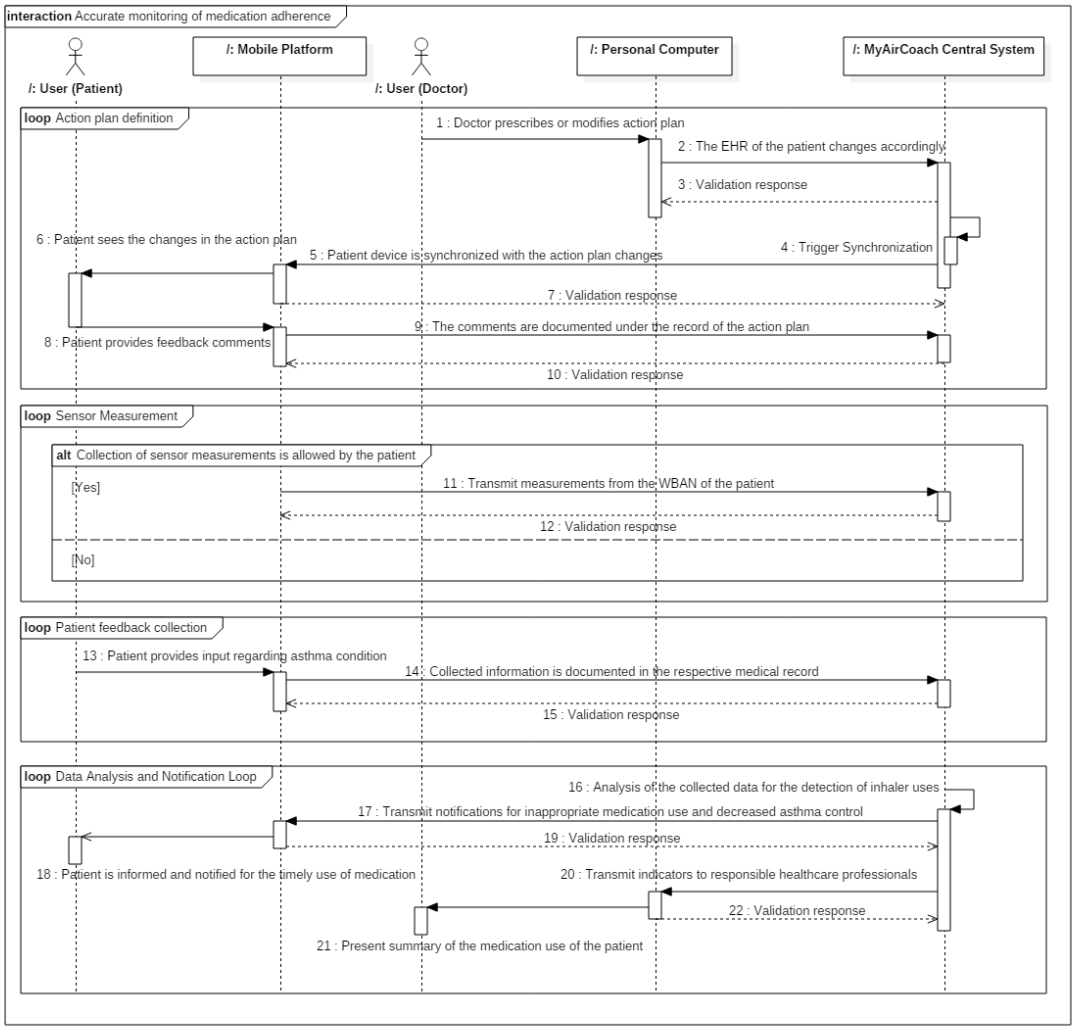
UC1.6 – Using the MyAirCoach system to monitor how regularly patients are taking (or not) their medication

Generic Description	
Use Case Name	*UC1.6 Using the myAirCoach system to monitor how regularly patients are taking (or not) their medication.*
Version	*V1.0*
Authors	*ICL*
Last Update	*December 2015*
Brief Description	*The myAirCoach system will be capable of logging when patients forget to take the prescribed medications and whether they are taking them properly (i.e. wrong day, hour, dose). Furthermore, the system will be able to detect a frequent use of rescue medications (i.e. salbutamol) as a sign of poor asthma control, which may require a change in the treatment strategy.*
Assumptions & Pre-	- *The myAirCoach system is installed on the patient's inhaler*

Conditions	*devices.* - *The myAirCoach Analytics components are capable of recording time and features of medication usage* - *The myAirCoach system provides alerts to the patients to warn them about inappropriate use of medications or poor asthma control* - *The myAirCoach system suggests actions to be taken*
Goal (Successful End Condition)	- *Patient is alerted to poor adherence to taking their asthma treatment plan medication*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs*
Involved Actors	- *Patients* - *Healthcare professionals*
Use Case Initiation	*Patient and healthcare professional inputs their treatment plan*
Main Flow	1. *Treatment plan is set by patient and/or healthcare team* 2. *The myAirCoach system records any drug consumption with specific details regarding the time of use for controller and reliever inhalers.* 3. *Data are automatically transferred to a secure database* 4. *Data are matched with prescriptions of clinicians and asthma guidelines* 5. *The myAirCoach GUI informs the patient about inappropriate use of medication or poor asthma control* 6. *The myAirCoach GUI suggests to the patient the most appropriate actions to be taken* 7. *Present a medication adherence summary to the responsible practitioner when required.*
Relationships with other Use Cases	*UC1.7, UC3.2*
Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP3, WP4, WP5*
Privacy & Regulation restrictions	*None*
Environmental restrictions	*None*
Quality of service indicators	- *Improved adherence to treatment* - *Improved therapy effectiveness* - *Improved asthma control* - *Reduced side and/or adverse effects*

References (optional)	*None*
Notes (optional)	*None*

UML Sequence Diagram

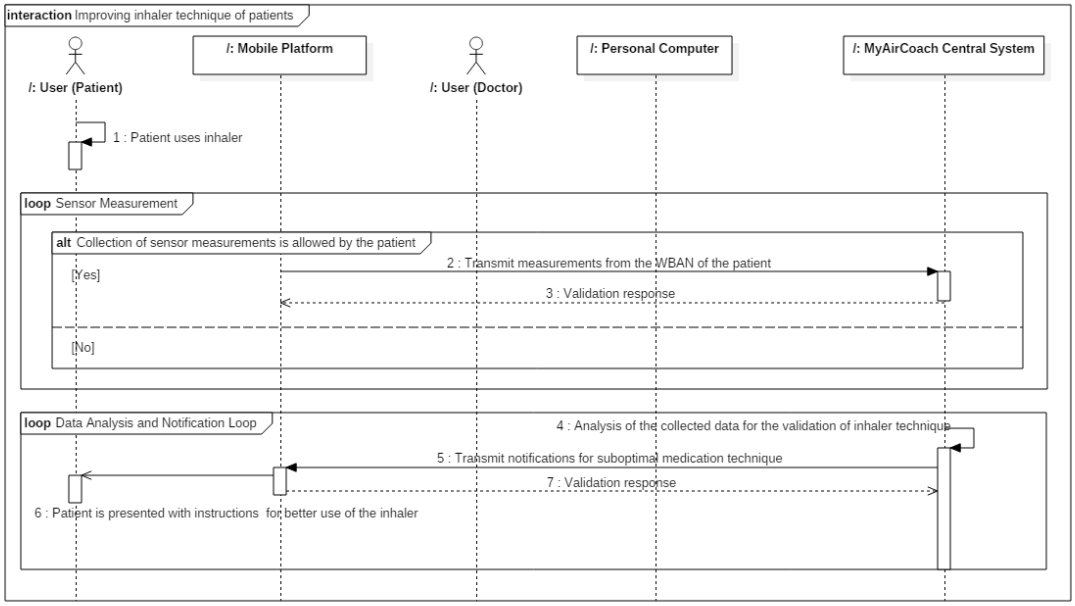


UC1.7 – MyAirCoach system alerts patient to improper inhaler technique

Generic Description	
Use Case Name	*UC1.7 myAirCoach system alerts patient to improper inhaler technique and provides an educational intervention for the optimal inhaler technique.*
Version	*V1.0*
Authors	*UMAN, CERTH, Allertec*
Last Update	*December 2015*
Brief Description	*It is well known that some asthma patients have poor inhaler technique.Poor inhaler technique may lead to poor asthma control as the medication fails to reach the desired target. The myAirCoach system could be used to offer assistance and education regarding the correct inhaler technique that should be used whilst alsoproviding patients with immediate feedback on their technique.*
Assumptions & Pre-Conditions	– *The myAirCoach system is capable of assessing inhaler technique according to the collection of data measurements* – *The myAirCoach system is able to supplyinstructions/demonstrations on how to use their inhaler device following improper use*
Goal (Successful End Condition)	– *Patients receives notification of improper inhaler technique and can utilise the educational materials to improve their technique*
Post-Conditions	- *The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	– *Patient*
Use Case Initiation	– *Patient uses their inhaler improperly*
Main Flow	1. *Patient uses inhaler* 2. *myAirCoach analyses the inhaler technique based on the collection of the measurements from the sensors* 3. *In the case of improper inhaler technique alerts and educational notifications should be provided* 4. *A link to instructions and/or a demonstration of correct inhaler technique is sent to the patient* 5. *Patient responds to instructions/demonstration and addresses their poor technique accordingly*
Relationships with other Use Cases	*UC 1.6*
Specific Description	

Relevance to MyAirCoach WPs	*WP1, WP3, WP4, WP5*
Privacy & Regulation restrictions	– *None*
Environmental restrictions	– *The device should be capable of detecting improper inhaler technique in a range of noisy environments*
Quality of service indicators	– *Patients receives immediate feedback of incorrect inhaler technique and is provided with educational materials/instructions to how to improve it*
References (optional)	– *None*
Notes (optional)	– *None*

UML Sequence Diagram



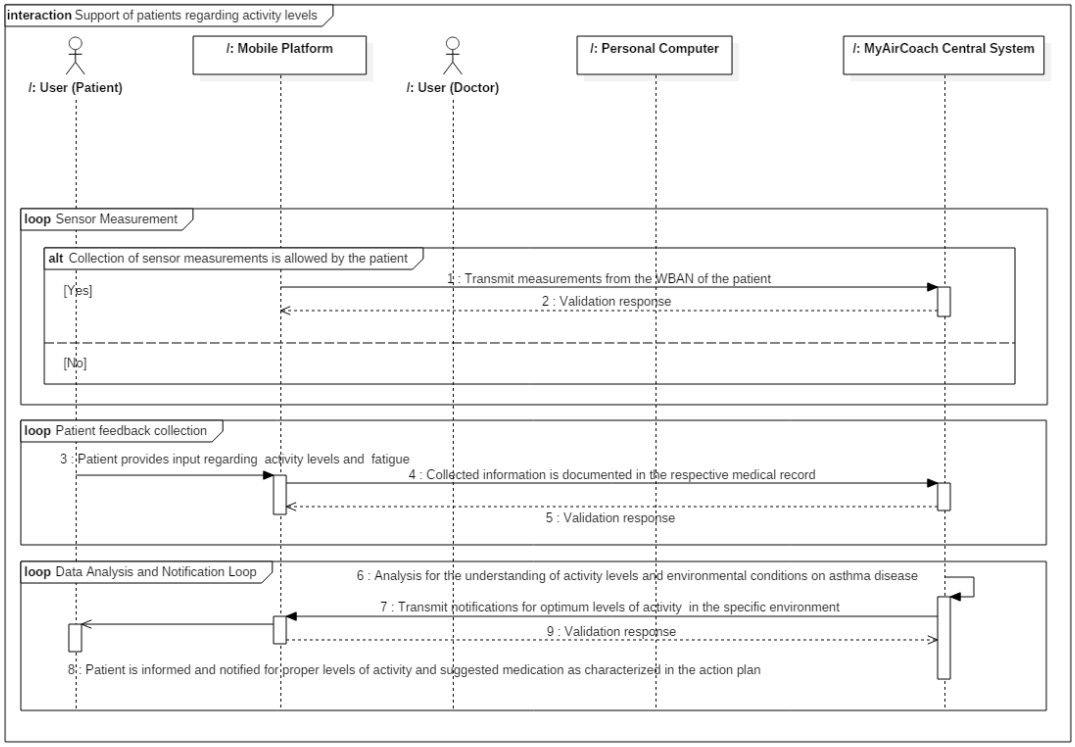
UC1.8 – Using the MyAirCoach system to monitor patients' physical activity and its impact on asthma control

Generic Description	
Use Case Name	*UC1.8 Using the myAirCoach system to monitor patients' physical activity and its impact on asthma control*
Version	*V1.0*
Authors	*ICL*
Last Update	*December 2015*
Brief Description	*A patient could benefit from the myAirCoach system to objectively assess the impact of practicing physical activity on asthma control. Moreover the myAirCoach system would allow patients to exercise in safe environments promptly informing*

	them about high concentrations of inhalant allergens, irritants and pollutants, as well as air temperature and humidity which could trigger asthma symptoms
Assumptions & Pre-Conditions	- *The MyAirCoach architecture components and devices are successfully integrated.* - *The MyAirCoach Analytics component are capable of loading environmental measurements and combine them with patients' clinical data* - *The implemented MyAirCoach GUI provides all the necessary interfaces for the presentation to the user of personalised alerts and instructions.*
Goal (Successful End Condition)	- *Patients receive advice on maintaining healthy level of physical activity* - *Patients receive advice on how to effectively manage their asthma when performing exercise*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs*
Involved Actors	- *Patients* - *Healthcare professionals*
Use Case Initiation	*This Use case initiates when a patient performs physical activity*
Main Flow	1. *The user allows the collection of multisensorial data (e.g. location) and activity level indicators (e.g. mobile phone accelerometer) and the intention of the user regarding exercise* 2. *The environmental sensor measurements are sent to the central system while web information from meteorological data is also provided to the system.* 3. *The patient information is transmitted from the mobile platform to the central DSS system.* 4. *The measurements are combined with the clinical record of the patient.* 5. *The systems registers the need of the patient to use medication before or after physical activity* 6. *The aggregated data are analysed and specific prediction risks and factors are calculated.* 7. *The myAirCoach GUI informs the patient about the related risks and the suggested activity level for the avoidance of asthma attacks* 8. *The myAirCoach GUI informs the patient about the optimal medication to use in order to minimise all safety risks and prevent exacerbations.*
Relationships with other Use Cases	*UC1.1*

Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP3, WP4, WP5*
Privacy & Regulation restrictions	*None*
Environmental restrictions	*Not suitable for aquatic sport disciplines*
Quality of service indicators	- *Encourage patients to practice physical activity* - *Allow patients to exercise in safe conditions*
References (optional)	*None*
Notes (optional)	*None*

UML Sequence Diagram



4.2.2.2 The patient's family (care givers) oriented use cases

The current section includes the use cases that include functionalities that will support the family or care givers of patients with asthma

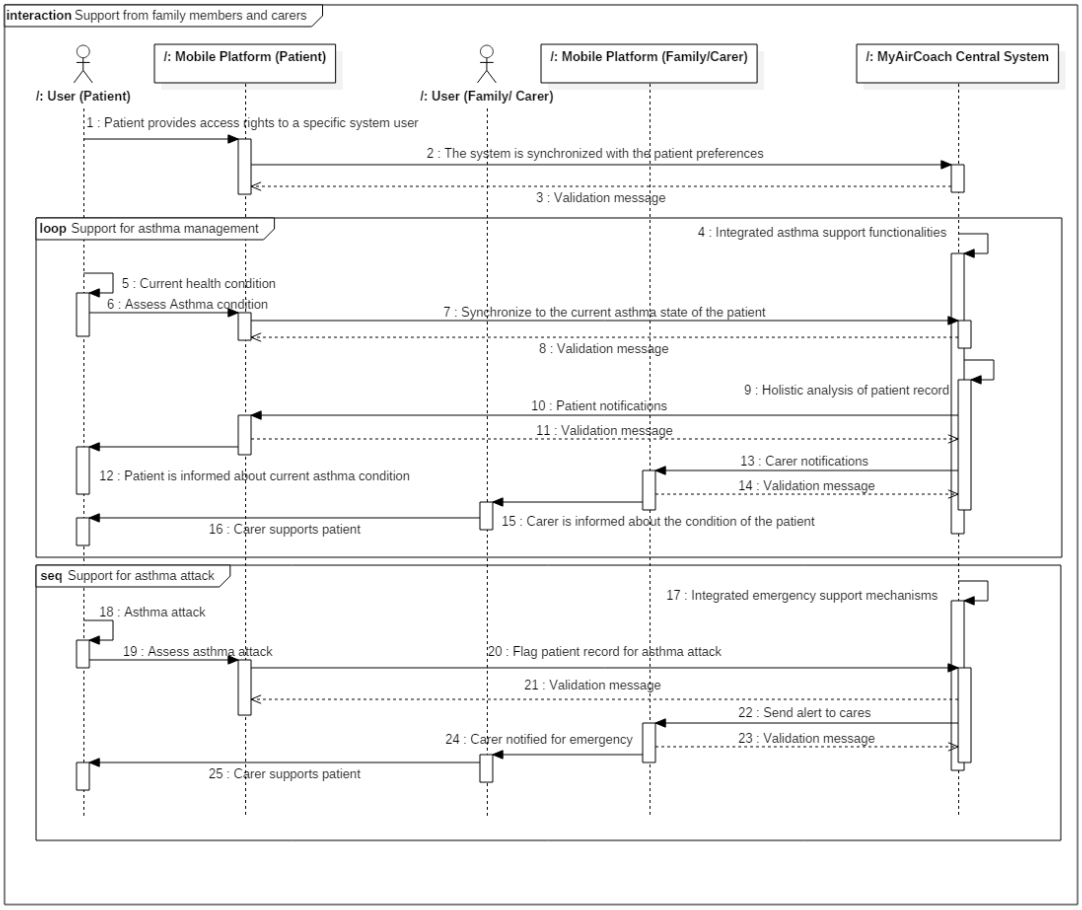
UC2.1 – Feedback of asthma state to family members or carers of patients with asthma

Generic Description	
Use Case Name	*UC2.1 Feedback of asthma state to family members or carers of patients with asthma*

Version	*V1.0*
Authors	*UMAN*
Last Update	*December 2015*
Brief Description	*A patient who requires assistance with their asthma management (e.g., younger children and the elderly) may elect for their data to be shared directly with a family member or care giver. This may include notifications of changes in current asthma state, medication usage etc. Family members/care givers are then better able to assist the patient with the management of their asthma.*
Assumptions & Pre-Conditions	- *The myAirCoach system is capable of collecting clinically relevant data and producing asthma indicators that can support the patients' families to help the effectively (e.g., measurement of asthma symptoms and calculation of asthma indicators)* - *The myAirCoach system is capable of notifying a third party of changes in a patient's asthma status*
Goal (Successful End Condition)	- *Family members or care givers receive updates regarding the current status of the user's asthma*
Post-Conditions	- *The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	- *Patient* - *Family member / care giver*
Use Case Initiation	- *Patient sets up regular notifications to be sent to a designated 3rd party (i.e., family member or care giver)*
Main Flow	1. *The patient gives access to his/her medical record to another user of the system.* 2. *The identified user receives notifications and alerts indicating the asthma state of the patient* 3. *The user takes proper action for the support of the patient either indirectly (through advice or discussions) or directly (fast response in the case of asthma attack)*
Relationships with other Use Cases	*UC2.2*
Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP2, WP3, WP4, WP5*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local databases or transmitted outside the framework of the central myAirCoach system* - *Data/notification should only be sent to designated individuals with the consent of the patient*

Environmental restrictions	- *None*
Quality of service indicators	- *Family members / care givers receive regular notifications regarding the patients asthma status*
References (optional)	- *None*
Notes (optional)	- *None*

UML Sequence Diagram



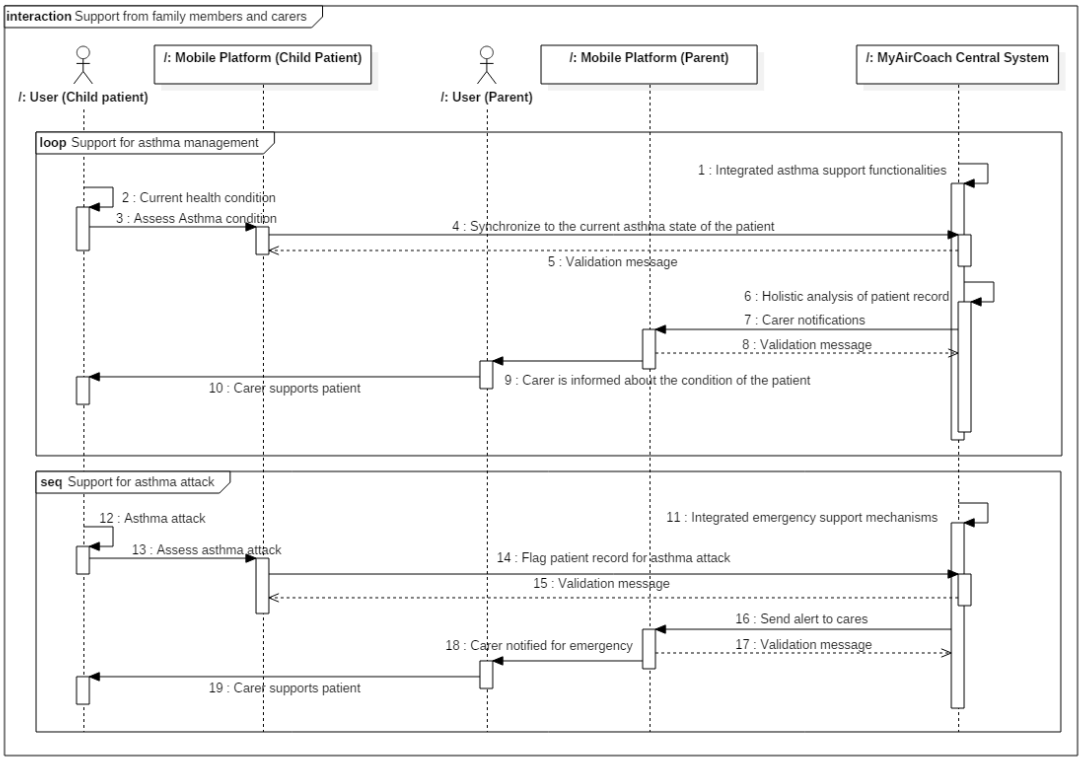
UC2.2 – Using the MyAirCoach system to support parents in ensuring adherence to treatment in their children

Generic Description	
Use Case Name	*UC2.2 Using the myAirCoach system to support parents in ensuring adherence to treatment in their children*
Version	*V1.0*
Authors	*ICL*
Last Update	*December 2015*

Brief Description	*The myAirCoach system could help parents to improve their child's compliance to treatment through a more active and enjoyable involvement. The myAirCoach system could also guarantee that children disease monitoring and treatment compliance is adequately respected even when not at home (i.e. when at school, during holidays, if abroad)*
Assumptions & Pre-Conditions	- *The myAirCoach system is capable of collecting functional and clinical data* - *The myAirCoach system guarantee an active and enjoyable involvement through user-friendly interfaces and gaming supports* - *The myAirCoach system is capable of notifying data to a third party*
Goal (Successful End Condition)	- *Notifications sent to family members and/or care givers*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	- *Patients* - *Family members and care givers*
Use Case Initiation	*Patient sets up regular notifications to be sent to a designated 3rd party (i.e. family member or care giver)*
Main Flow	1. *Parents can supervise the health condition of their young children* 2. *Parents receives notification and alerts indicating the asthma state of the patient* 3. *Parents support their children either indirectly (through advice or discussions) or directly (fast response in the case of asthma attack)*
Relationships with other Use Cases	*UC2.1*
Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP3, WP4, WP5*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local database or transmitted outside the framework of the central myAirCoach system* - *Data/notification should only be sent to designated individuals*
Environmental restrictions	*None*

Quality of service indicators	*Improve management of paediatric asthma*
References (optional)	*None*
Notes (optional)	*None*

UML Sequence Diagram



4.2.2.3 Healthcare professional oriented use cases

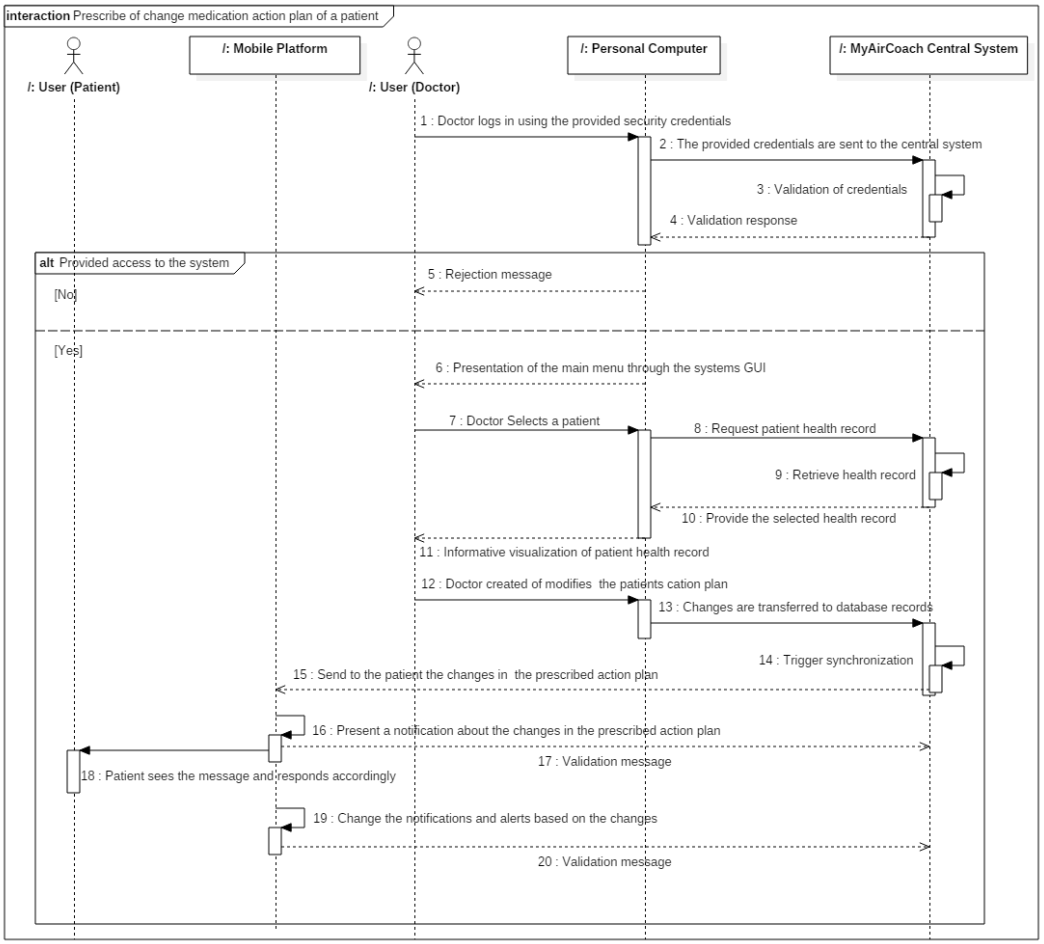
The current section includes the use cases that include functionalities that will support doctors and healthcare professionals for the efficient and effective support of their patients through the informative presentation of information and the MyAirCoach decision support system

UC3.1 – Creating and/or providing modifications to the action plan of a patient

Generic Description	
Use Case Name	*UC3.1 – Creating and/or providing modifications to the action plan of a patient*
Version	*V1.0*
Authors	*CERTH, Allertec and all medical partners*
Last Update	*December 2015*

Brief Description	*The doctor logs in the myAirCoach system and selects the tool for supervision of patients of his/her responsibility. The doctor selects a specific patient and choses to add/edit the prescribed action plan. A variety of options are given to the doctor for the definition of the timing and doses of medication. Doctor saves the action plan. Patient's record is updated and a notification is send to the patient's mobile device. Patient checks the message and responds to the changes accordingly.*
Assumptions & Pre-Conditions	- *The myAirCoach architecture components should be successfully integrated.* - *The myAirCoach system should be installed to the doctor's computer.* - *The GUI provides the necessary interfaces for doctors to assess the records of patients and modify their prescribed action plan.* - *The myAirCoach system should be capable of loading the patient's medical record in order to use for the prescription process.* - *The myAirCoach system should be installed to the patient's smart device.* - *The myAirCoach GUI provides the necessary interfaces for the presentation of alerts and instructions on patient's side.*
Goal (Successful End Condition)	- *The doctor can efficiently assess the medical history of the patient* - *The doctor can prescribe or change the medication action plan of patients in her/his responsibility.* - *The patient is informed efficiently for any changes in her/his prescribed action plan.* - *The patient is informed in a timely manner for the proper use of medication.*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	*Healthcare professional* *Patient*
Use Case Initiation	*This Use Case is initiated after the request of the doctor*
Main Flow	1. *The doctor logs in the MyAirCoach system* 2. *The doctor chooses to review the medical record of a specific patient* 3. *The doctor chooses to add or modify the medication action plan of the patient* 4. *The record of the patient is changed* 5. *A notification is send to the patient for the changes in his/her medication action plan* 6. *Notification and decision support on the patient's side are*

	adapted to the new medication regimen
Relationships with other Use Cases	*UC1.1, UC1.5*
Specific Description	
Relevance to MyAirCoach WPs	*WP4, WP5*
Privacy & Regulation restrictions	*The loaded patient data should not be stored to any local databases or transmitted outside the framework of the central MyAirCoach system.*
Environmental restrictions	*No environmental restrictions.*
Quality of service indicators	*Ability of doctors to change medication action plans based on the response of the patients.* *Ability of doctors to communicate the changes to the patients without the use of traditional communication channels and through the privacy preserving framework of the MyAirCoach system.* *Ability of patients to receive notifications and follow the changes in their action plan, without the need to visit the clinic or hospital*
References (optional)	*No references are noted.*
Notes (optional)	*No additional notes*
UML Sequence Diagram	



UC3.2 – Using the inhaler measurements to supervise the patient's adherence to the prescribed action plan

Generic Description	
Use Case Name	*UC3.2 – Using the inhaler measurements to supervise the patient's adherence to the prescribed action plan.*
Version	*V1.0*
Authors	*CERTH*
Last Update	*December 2015*
Brief Description	*The patient uses the smart MyAirCoach inhaler device which accurately detects the actuation process. The patient's record is updated and includes all past detected actuations. This history of medication use is compared with the prescribed action plan and if the adherence is below the requirements an alert is presented to both doctor and patient*
Assumptions & Pre-Conditions	- *The MyAirCoach architecture components should be successfully integrated.* - *The MyAirCoach system should be installed to the doctor's*

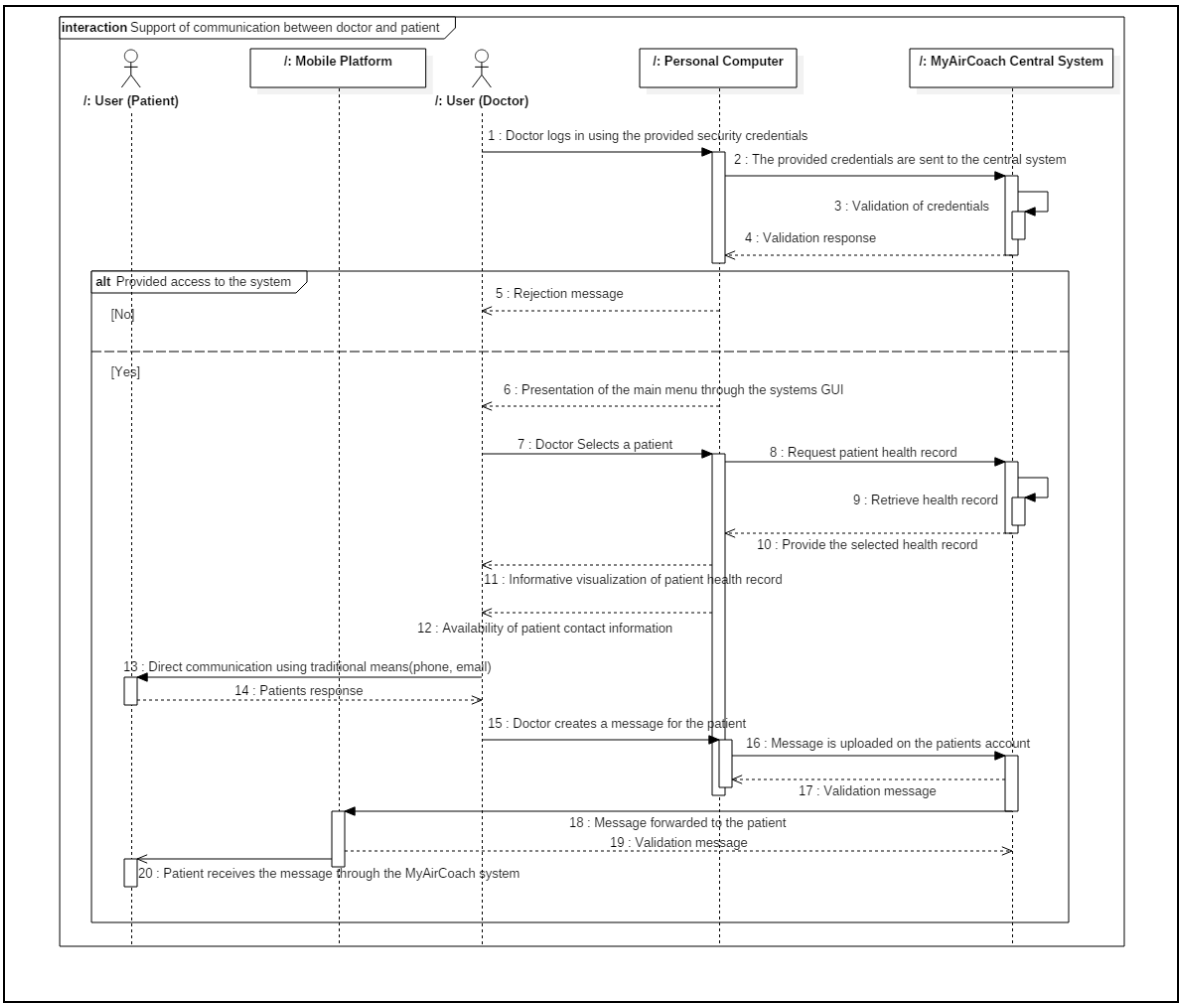
	computer. - *The GUI provides the necessary interfaces for doctors to view notifications and alerts about the medication adherence of their patients.* - *The MyAirCoach system should be installed to the patient's smart device.* - *The MyAirCoach GUI provides the necessary interfaces for the presentation of alerts and instructions on patient's side.*
Goal (Successful End Condition)	- *The doctor can efficiently assess the level of medication adherence for all patients of her/his responsibility.* - *Doctors can respond with changes in the medication action plan when the patient cannot follow the prescription.* - *The patient are helped to follow their prescribed action plan and do not forget to take their medications.*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	*Doctor/medical professional and Patient*
Use Case Initiation	*This Use Case is initiated after the use of inhaler*
Main Flow	1. *The patient uses the MyAirCoach smart inhaler* 2. *The actuation event is detected* 3. *Patient record of inhaler use is adapted accordingly* 4. *The use history of medication use is compared with the prescribed action plan* 5. *In case of inconsistencies below the minimum requirements notifications are send to both patient and doctor* 6. *Patient is supported with instructions for the use of medication and the importance of its timely use*
Relationships with other Use Cases	*UC1.6*
Specific Description	
Relevance to MyAirCoach WPs	*WP3, WP4, WP5*
Privacy & Regulation restrictions	*The loaded patient data should not be stored to any local databases or transmitted outside the framework of the central MyAirCoach system.*
Environmental restrictions	*No environmental restrictions.*
Quality of service indicators	*Ability of doctors to accurately monitor the adherence of patients to the prescribed medication action plan.*

	Ability of doctors to adapt the prescriptions to the actual needs of patients. *Ability of patients to receive alerts and help in order to maintain the optimum medication regimen*
References (optional)	*No references are noted.*
Notes (optional)	*No additional notes*
UML Sequence Diagram	*The current use case is covered in the UML diagram of UC1.6*

UC3.3 – A healthcare professional could access patient's data in order to provide a patient with feedback remotely (i.e over the phone or via e-mail)

Generic Description	
Use Case Name	*UC3.3 A healthcare professional could access patient's data in order to provide a patient feedback remotely (i.e., over the phone or via e-mail)*
Version	*V1.0*
Authors	*UMAN*
Last Update	*December 2015*
Brief Description	*In the situation where a patient is required to visit their medical team for a routine check-up or due to a minor (asthma-related) complaint, a GP or healthcare professional could access the myAirCoach system and provide a patient with advice remotely. This could save a patient a trip to their GP practice or hospital, saving the patient time and reducing the strain on NHS services.*
Assumptions & Pre-Conditions	- *The myAirCoach system is capable of collecting clinically relevant data (e.g., asthma symptoms and lung function data)* - *The myAirCoach system is capable of transferring data to a secure database* - *Healthcare professionals are able to access patients' data when they attend their medical appointment*
Goal (Successful End Condition)	- *A patient receives the advice they require without a physical visit to hospital/GP practice*
Post-Conditions	- *The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	- *Patient* - *Healthcare professional*

Use Case Initiation	- *Patient contacts their GP or healthcare provider and requests a remote consultation*
Main Flow	1. *The doctor logs in the MyAirCoach system* 2. *The doctor chooses to review the medical record of a specific patient* 3. *The doctor chooses to access the contact information of the patients and communicates with him/her by using traditional means of communication (e.g. phone, email)* 4. *Alternatively the doctor can upload a message on the patient's account in the MyAirCoach system* 5. *The record of the patient is changed and the message is forwarded to the patients device under the MyAirCoach application* 6. *Patient receives the message and responds accordingly*
Relationships with other Use Cases	*UC1.3, UC3.5*
Specific Description	
Relevance to MyAirCoach WPs	*WP1, WP2, WP3, WP4, WP5*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local databases or transmitted outside the framework of the central myAirCoach system*
Environmental restrictions	- *None*
Quality of service indicators	- *The patient is provided with the advice and guidance remotely (i.e., without the need for a face-to-face meeting).*
References (optional)	- *None*
Notes (optional)	- *None*
UML Sequence Diagram	



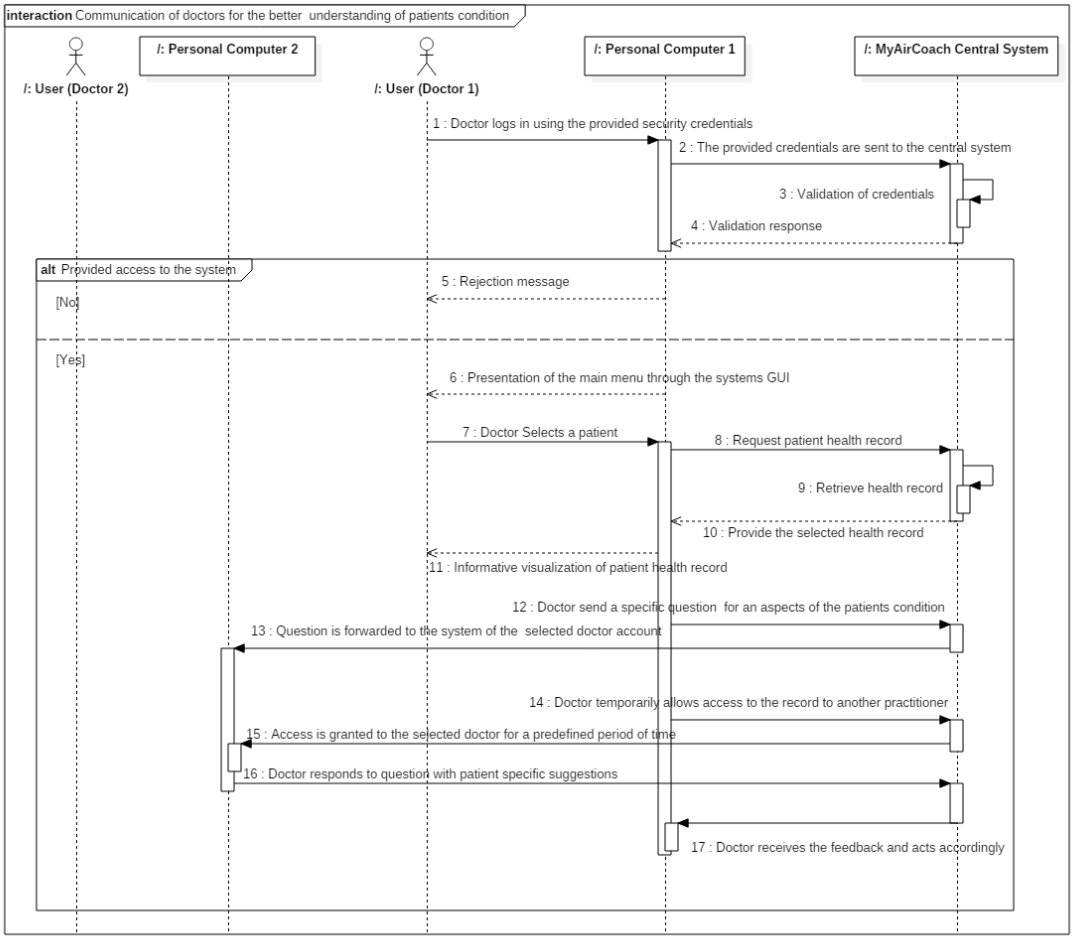
UC3.4 – Using the MyAirCoach system could facilitate GP's to interact with specialists and increase their awareness of asthma diagnosis management

Generic Description	
Use Case Name	*UC3.4 Using the myAirCoach system could facilitate GP's to interact with specialists and increase their awareness of asthma diagnosis and management*
Version	*V1.0*
Authors	*ICL*
Last Update	*December 2015*
Brief Description	*The myAirCoach system could allow an easy flow and exchange of patients' clinical and functional data between specialists and GP's. This would enable GP's to base their clinical decisions not only on their knowledge and experience but also on a broad panel of parameters collected through methodologies not available at their office. Furthermore, a direct channel with specialists in allergic and respiratory diseases would allow GP's to increase their awareness of asthma diagnosis and management. Such approach would optimise the number and*

	related costs of healthcare visits
Assumptions & Pre-Conditions	- *The myAirCoach Analytics components are capable of recording clinical and functional parameters* - *The myAirCoach system is capable of transferring data to a secure database* - *The myAirCoach system provides all the necessary interfaces for the presentation of data to the users*
Goal (Successful End Condition)	- *Improve interactions between GP's and specialists* - *Increase GP's awareness of asthma diagnosis and management*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs*
Involved Actors	- *Patients* - *GP's* - *Specialists*
Use Case Initiation	*This Use Case occurs in the management of asthma patients by GP's*
Main Flow	1. *The doctor logs in the MyAirCoach system* 2. *The doctor chooses to review the medical record of a specific patient* 3. *The doctor shares the record with another doctor and asks for his feedback in regards to specific aspects of asthma disease and prescribed medication* 4. *An option is given to the doctor to share an anonymised version of the record when required*
Relationships with other Use Cases	-
Specific Description	
Relevance to MyAirCoach WPs	*WP3, WP4, WP5*
Privacy & Regulation restrictions	*Patient data should not be copied or stored to any local database and transmitted outside the network of the myAirCoach system*
Environmental restrictions	*None*
Quality of service indicators	*Interactions between GP's and specialists* *Information provided by specialists to GP's*
References (optional)	*None*

Notes (optional)	*None*

UML Sequence Diagram



UC3.5 – The MyAirCoach system can be used for the effective follow-up of patients

Generic Description	
Use Case Name	*UC.3.5 The myAirCoach system used as a platform for the effective follow-up of patients*
Version	*V1.0*
Authors	*UMAN*
Last Update	*December 2015*
Brief Description	*Patients leaving hospital or their GP services with new medication are often asked to return for follow-up appointments to ensure that the new medication is effective and without side effects. The myAirCoach system could provide a platform to do this without the need for follow-up visit(s). Indeed, the myAirCoach system could be given to patients to record clinically*

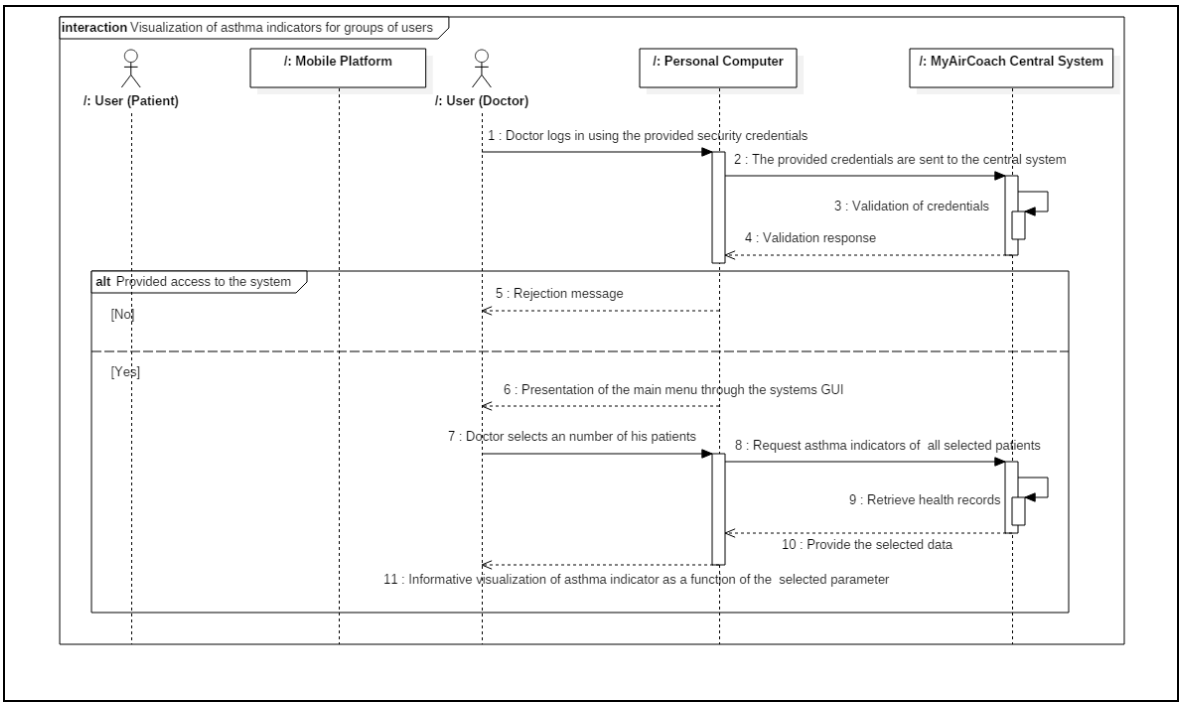
	relevant markers of medication effectiveness and side-effects. This data could then be reviewed by their medical team (or automatically) instead of requiring a patient to attend a follow-up visit, thus significantly reducing healthcare costs and improving time-efficiency for the patient.
Assumptions & Pre-Conditions	- *The myAirCoach system is capable of collecting clinically relevant data (e.g., asthma symptoms and lung function data)* - *The myAirCoach system is capable of transferring data to a secure database* - *Healthcare professionals are able to access patients' data*
Goal (Successful End Condition)	- *A patient utilises the myAirCoach system following discharge from hospital/GP services in place of follow-up visits*
Post-Conditions	- *The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	- *Patients* - *Healthcare professional*
Use Case Initiation	- *A patient is discharged from hospital/GP services and is asked to use the myAirCoach system to record asthma symptoms, clinically relevant markers and side-effects of their new medication*
Main Flow	1. *A patient leaves hospital or healthcare services and is asked to record asthma symptoms, clinically relevant markers and side-effects of new medication using the myAirCoach system* 2. *A patient uses the myAirCoach system to collect symptoms and clinical relevant data regarding their asthma* 3. *Data are automatically transferred to a secure database* 4. *The healthcare team is able to access the data* 5. *The data is provided with a suitable interface for determining medication effectiveness/side effects* 6. *Contact details for the patient are provided allowing for the healthcare to contact the patient and provide them with advice should it be required*
Relationships with other Use Cases	*UC3.3*
Specific Description	
Relevance to MyAirCoach WPs	- *WP1, WP2, WP3, WP4, WP5*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local databases or transmitted outside the framework of the central myAirCoach system*

Environmental restrictions	- *None*
Quality of service indicators	- *A patient utilises the myAirCoach system in place of attending follow-up visits*
References (optional)	- *None*
Notes (optional)	- *None*
UML Sequence Diagram	*The current use case is covered in the UML diagram of UC3.1 and is considered a specialised version of that example that focuses on the follow up of patients that had to be hospitalised due to asthma worsening.*

UC3.6 – Using the MyAirCoach system to identify intra and inter-patient reliable predictive markers of asthma worsening and exacerbations

Generic Description	
Use Case Name	*UC3.6 Using the myAirCoach system to identify intra- and inter-patient reliable predictive markers of asthma worsening and exacerbations*
Version	*V1.0*
Authors	*ICL*
Last Update	*December 2015*
Brief Description	*Clinicians could access the myAirCoach database to identify, among clinical and functional registered parameters, those markers which could represent, individually or in combination, reliable predictive markers of asthma worsening and exacerbations at both intra- and inter-patient levels*
Assumptions & Pre-Conditions	- *The myAirCoach system is capable of collecting clinically relevant data (e.g. asthma symptoms and lung function data)* - *The myAirCoach system is capable of transferring data to a secure database* - *Healthcare professionals are able to access both patients' data and computational models*
Goal (Successful End Condition)	- *Allow an early diagnosis* - *Improve asthma control* - *Reduce exacerbations*
Post-Conditions	*The system maintains its stability and it is able to respond to new inputs.*
Involved Actors	- *Patients*

	- *Healthcare professionals*
Use Case Initiation	*This Use Case occurs when healthcare professionals access the myAirCoach database*
Main Flow	1. *The doctor logs in the MyAirCoach system* 2. *The doctor chooses to review the medical records of a number of his/her patients* 3. *The selected asthma indicators are plotted as a function of a selected parameter in order to help doctors detect significant patterns in condition of their patients* 4. *Support the identification of predictive markers of asthma worsening and exacerbations at intra-patient and inter-patient levels*
Relationships with other Use Cases	
Specific Description	
Relevance to MyAirCoach WPs	*WP3, WP4, WP5*
Privacy & Regulation restrictions	*Patient data should not be copied or stored in any local database and transmitted outside the network of the myAirCoach system*
Environmental restrictions	*None*
Quality of service indicators	*Feedback by healthcare professionals* *Asthma control* *Occurrence of exacerbations*
References (optional)	*None*
Notes (optional)	*None*
UML Sequence Diagram	



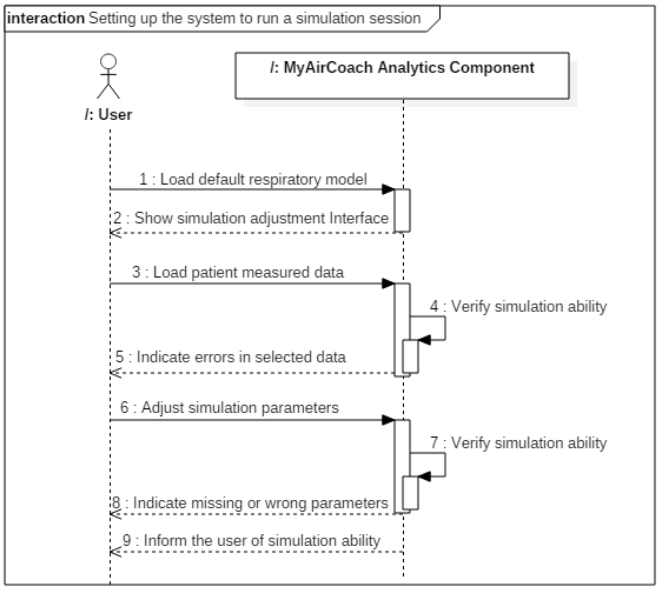
4.2.2.2 Research oriented use cases

The current section describes use cases that include functionalities that will support researchers for the understanding of asthma disease and the identification of important risk factors and physiological markers.

UC4.1 – Setting up the system to run a simulation session

Generic Description	
Use Case Name	*UC4.1 – Setting up the system to run a simulation session*
Version	*V1.0*
Authors	*CERTH*
Last Update	*December 2015*
Brief Description	*The researcher loads a generalised respiration model and sets up the simulation parameters, e.g. timing of respiration, air parameters. The researcher then loads the patient data in order to personalise the default models (e.g. lung geometry or respiration profile). The myAirCoach system should be able provide assistance via the GUI for how each parameter affects the simulation.*
Assumptions & Pre-Conditions	- *The myAirCoach architecture components should be successfully integrated.* - *The GUI provides the necessary adjustment controls to the user.* - *The myAirCoach Analytics component should be capable of loading patient measurement data in order*

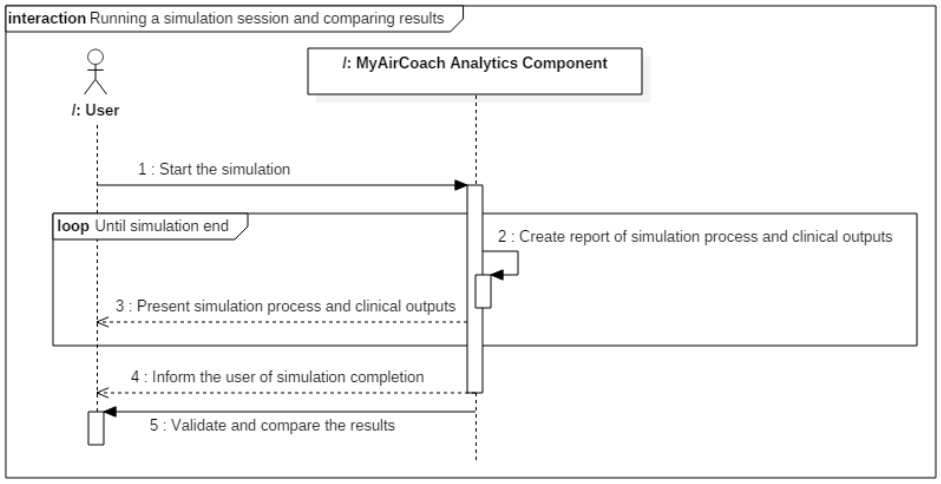
	personalise the simulation behaviour. - *The myAirCoach system should be installed to user's hardware base.*
Goal (Successful End Condition)	- *The patient measurement data are loaded successfully.* - *The parameterisation of the MyAirCoach system is completed in a reasonable time frame.*
Post-Conditions	- *The simulation components are ready to run after the parameterisation process.*
Involved Actors	- *Researcher*
Use Case Initiation	- *This Use Case is initiated after the user finalises the patient data measurement.*
Main Flow	1. *The user loads the default respiratory myAirCoach models.* 2. *The user loads the patient measurement data* 3. *The user adjusts the simulation parameters when required.* 4. *The myAirCoach GUI informs the user that the simulation session is ready to run.*
Relationships with other Use Cases	*UC4.2, UC4.3, UC4.4*
Specific Description	
Relevance to MyAirCoach WPs	*WP4,WP5*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local databases and have to be discarded from the system memory after the myAirCoach application is terminated.*
Environmental restrictions	- *No environmental restrictions.*
Quality of service indicators	*Successful loading of the patient's data.* *The setting up procedure is easy to be performed in terms of usability and performance.*
References (optional)	- *No references are noted.*
Notes (optional)	-
UML Sequence Diagram	



UC4.2 – Running a simulation session and comparing results

Generic Description	
Use Case Name	*UC4.2 – Running a simulation session and* comparing *the results of different simulation sessions*
Version	*V1.0*
Authors	*CERTH*
Last Update	*December 2015*
Brief Description	*The user runs a simulation session based on the loaded model of the patient (lung geometry of respiration profile). The Simulation Platform informs the user at every simulation step by depicting informative diagrams and visualisation of important clinical parameters including air flow, air pressure and particle concentrations. After the simulation, a report is displayed to user containing analytical information regarding the patient's respiration. The user is able to match the patient to a specific group and understand better the airflows within the lung airways*
Assumptions & Pre-Conditions	- *The myAirCoach architecture components should be successfully integrated.* - *The GUI is able to provide informative visualisation of the simulation state in terms of important clinical parameters.* - *The models and the patient's data are already loaded (pre-condition).*
Goal (Successful End Condition)	- *The simulation cycle model is performed without any errors.* - *The result is depicted to the user in a comprehensive and*

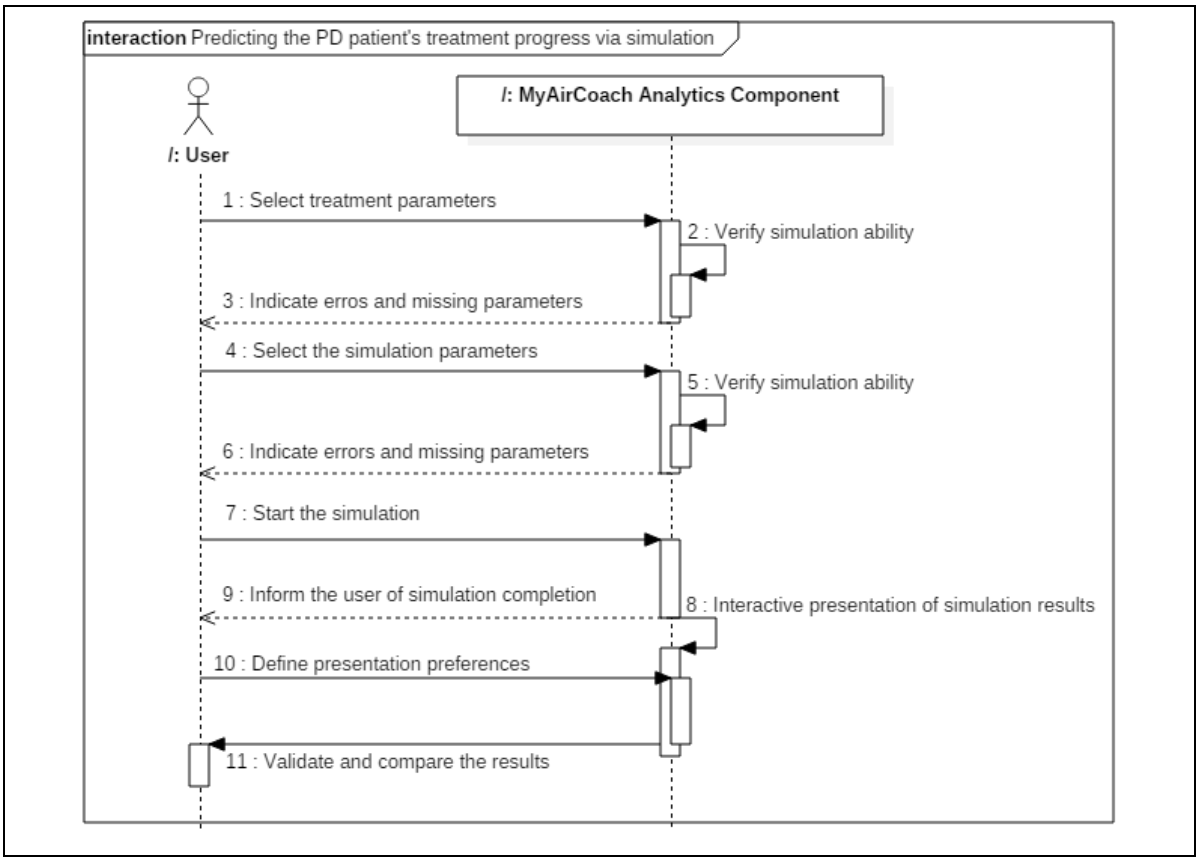
	understandable way. - *The defined validation protocol succeeds.*
Post-Conditions	*The visualisation components are ready to perform data comparisons or predict the evolution of the disease.*
Involved Actors	*Clinician/medical professional, researcher/expert.*
Use Case Initiation	*This Use Case is initiated after the user loads the patient models and sets up the simulation parameters.*
Main Flow	1. *The user starts the simulation.* 2. *The system depicts the state of processes while running the simulation.* 3. *The system informs the user when the simulation is finished and update its GUIs.* 4. *The user validates the results and compares it to the other stored simulation results.*
Relationships with other Use Cases	*UC4.1, UC4.3*
Specific Description	
Relevance to MyAirCoach WPs	*WP4,WP5*
Privacy & Regulation restrictions	*No privacy or regulation restrictions.*
Environmental restrictions	*No environmental restrictions.*
Quality of service indicators	*Validation of the simulation result.*
References (optional)	*No references are noted.*
Notes (optional)	-
UML Sequence Diagram	



UC4.3 – Predicting the patient's treatment progress via simulation

Generic Description	
Use Case Name	*UC4.3* – Predicting the patient's treatment progress via simulation
Version	*V1.0*
Authors	*CERTH*
Last Update	*December 2015*
Brief Description	*This use case refers to the capability of the myAirCoach system framework to predict the patient's progress using the current treatment parameters. The user selects the patient's profile and uploads to the system the observation data (lung geometry and respiration characteristics). The myAirCoach runs a macro-scale simulation of medication flow within the airways and effective reaching of medication into the lungs. Using the produced results the researches will be effectiveness of the proposed treatment for the management of asthma disease.*
Assumptions & Pre-Conditions	- *The myAirCoach architecture components should be integrated.* - *The simulation processing times should be as short as possible.* - *The treatment parameters are valid.*
Goal (Successful End Condition)	- *The simulation is completed without any errors/inconsistencies.* - *The myAirCoach Analytics component should be capable of displaying to the researcher the asthma evolution through all stages of simulation.*

Post-Conditions	*Successful simulation results for template respiratory models.*
Involved Actors	*Clinician/medical professional, researcher/expert*
Use Case Initiation	*This Use Case is initiated with the need of predicting the patient's future disease state after receiving specific treatment.*
Main Flow	1. *The user fills the current treatment parameters, e.g. drug type and dosage.* 2. *The user loads a patient model including medical history as well as lung geometry and respiration profile.* 3. *The user sets up the simulation parameters, e.g. for how long in the future the simulation has to run, intervals, etc.* 4. *The user starts the simulation.* 5. *The simulation ends.* 6. *The output result is presented to the user in an interactive way so that the effectiveness of medication is summarised and easily understood.*
Relationships with other Use Cases	*UC4.1, UC 4.2*
Specific Description	
Relevance to MyAirCoach WPs	*WP4,WP5*
Privacy & Regulation restrictions	*No privacy or regulation restrictions.*
Environmental restrictions	*No environmental restrictions.*
Quality of service indicators	*The prediction result should have a large confidence factor.*
References (optional)	*No references are noted.*
Notes (optional)	-
UML Sequence Diagram	



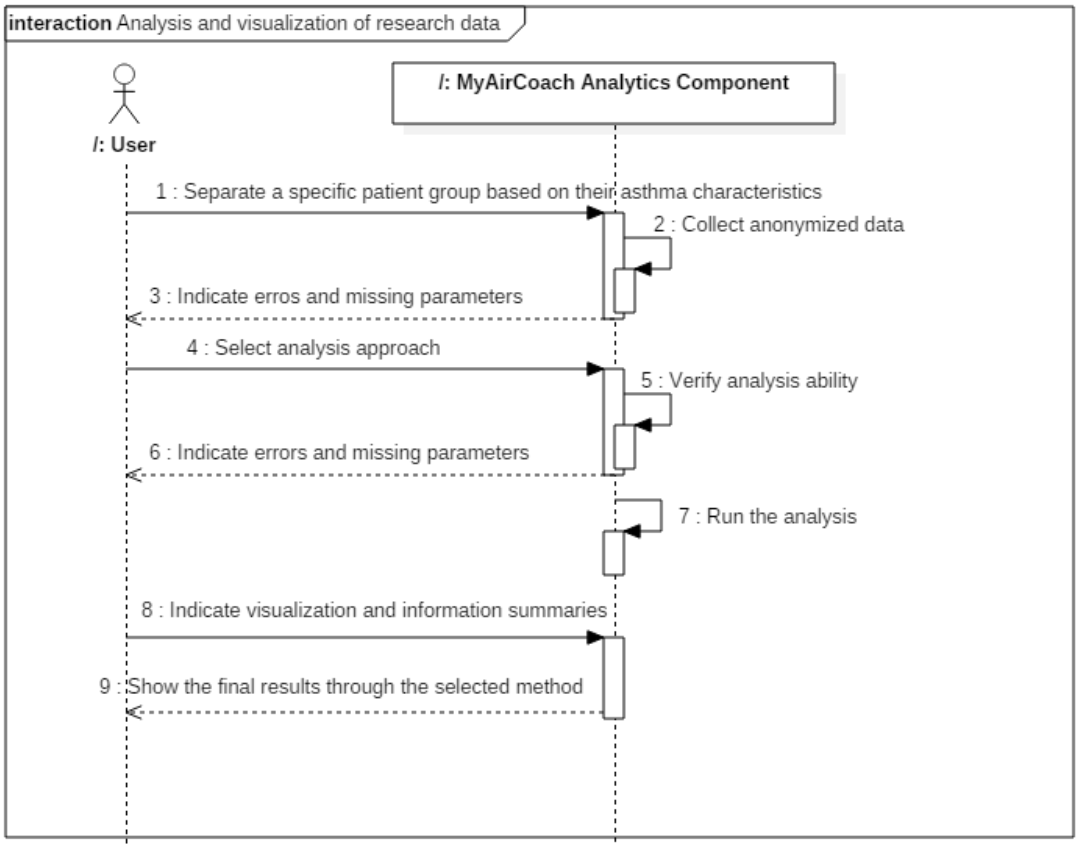
UC4.4 – Use of MyAirCoach to determine medication effectiveness and side-effect frequency

Generic Description	
Use Case Name	*UC4.4 Use of myAirCoach to determine medication effectiveness and side-effect frequency*
Version	*V1.0*
Authors	*UMAN*
Last Update	*December 2015*
Brief Description	*A researcher could use the myAirCoach system to compare medication, in terms of clinical benefits and medication side effects, using a cross-sectional study design. All patients using the myAirCoach system could have their data, in anonymised format, transferred onto the central myAirCoach database. This data will include the medication that they use along with recorded side effects and markers of asthma control/exacerbations.* *Data could be analysed by researchers to compare medications against each other, thereby determining the most effective treatment strategies. This could inform medical practice, improve patient treatment and could improve treatment cost effectiveness.*
Assumptions & Pre-Conditions	- The myAirCoach system can record patients medication usage - *The myAirCoach system is capable of collecting clinically*

	relevant data and medication side-effects - *The myAirCoach system is capable of transferring data to a secure database* - *Researchers are able to access database and run scripts to retrieve relevant data*
Goal (Successful End Condition)	- *A researcher is able to preform cross sectional analysis comparing different medication.*
Post-Conditions	- *None*
Involved Actors	- *Researchers* - *Patients*
Use Case Initiation	- *Researcher accesses myAirCoach central database and runs a script to retrieve relevant data*
Main Flow	1. *Patient using myAirCoach system agree to their anonymised data being used for research* 2. *Medication usage and clinically relevant data recorded and uploaded to central data base* 3. *Researcher accesses data base and retrieves the specific subsections of the data that are of his/her interest* 4. *Researcher is offered with analysis and visualisation functionalities that can help for the identification of important asthma patterns and support the understanding of asthma* 5. *Correlation capabilities connecting different parameters are provided for researchers to understand the effectiveness of medication and the results in the condition of asthma patients*
Relationships with other Use Cases	*UC4.1 UC4.5*
Specific Description	
Relevance to MyAirCoach WPs	*WP3, WP4, WP5*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local databases or transmitted outside the framework of the central myAirCoach system* - *Patients should consent for their data to be used for this purpose*
Environmental restrictions	- *None*
Quality of service indicators	- *Researchers able to retrieve data to assess medication effectiveness/side effect frequencies*

References (optional)	- *None*
Notes (optional)	- *None*

UML Sequence Diagram



UC4.5 – Using the MyAirCoach system to determine the seasonal variations in airway inflammation and asthma control

Generic Description	
Use Case Name	*UC4.5 Using the myAirCoach system to determine the seasonal variation in airway inflammation and asthma control*
Version	*V1.0*
Authors	*ICL*
Last Update	*03/12/2015*
Brief Description	*Researchers could use the myAirCoach database to assess seasonal variation in airway inflammation and asthma control, in order to identify triggers of symptoms, adjust the treatment strategy along the year, improve asthma control and consequently reduce exacerbations*
Assumptions & Pre-	- *The myAirCoach Analytics components are capable of*

Conditions	*recording functional and clinical parameters* - *The myAirCoach system is capable of transferring data to a secure database* - *Researchers are able to access database and run scripts to retrieve relevant data*
Goal (Successful End Condition)	- *Assess asthma seasonal variation* - *Improve asthma control*
Post-Conditions	*None*
Involved Actors	- *Researchers* - *Patients*
Use Case Initiation	*Researcher accesses the myAirCoach central database and analyse data*
Main Flow	*1 Patient using myAirCoach system agree to their anonymised data being used for research* *2 Medication usage and clinically relevant data recorded and uploaded to central data base* *3 Researcher accesses data base and retrieves the specific subsections of the data that are of his/her interest* *4 Researcher is offered with analysis and visualisation functionalities that can help for the identification of important asthma patterns and support the understanding of asthma* *5 Analysis capabilities of health history are provided for the support of researchers*
Relationships with other Use Cases	*UC4.4*
Specific Description	
Relevance to MyAirCoach WPs	*WP4,WP5*
Privacy & Regulation restrictions	*Patient data should not be copied or stored in any local database and transmitted outside the network of the myAirCoach system* *Patients should consent for their data to be used for this purpose*
Environmental restrictions	*None*
Quality of service indicators	*Researches are able to access and analyse patients' data*
References (optional)	*None*

Notes (optional)	*None*
UML Sequence Diagram	The UML diagram of the current use case is identical to the one provided in UC4.4. The two use cases are discriminated based on the types of analysis and visualisation that they are based upon.

UC4.6 – MyAirCoah system used to collect data for clinical trials

Generic Description	
Use Case Name	*UC4.6 – myAirCoach system used to collect data for clinical trials*
Version	*V1.0*
Authors	*UMAN*
Last Update	*December 2015*
Brief Description	*A researcher could use the myAirCoach system as a tool to collect data when designing clinical trials. The myAirCoach system will be capable of collecting and recording a variety of data often used as outcome measures during clinical trials [e.g., asthma control, lung function (FEV_1), FeNO]. At present, in studies requiring repeated/regular measurements, data are often recorded by patients in workbooks and are prone to recording errors, missing & lost data and falsified results.* *The myAirCoach system would be superior to paper records in several aspects.* *i) Data can be recorded electronically and automatically – reducing data input errors* *ii) Reminders can be sent to participants to take treatments and record measurements – reducing missed treatments and missing data* *iii) Data can be automatically stored – preventing lost data* *iv) Data can be time stamped – preventing the falsification of data (it is well known that participants fill in workbooks immediately prior to a study visit)* *Thus, the myAirCoach system will be beneficial with respect to the quality of a data recorded.*
Assumptions & Pre-Conditions	- *The myAirCoach system is capable of collecting clinical relevant data* - *The myAirCoach systems is capable of sending reminders to take treatments and/or measurements* - *The myAirCoach system is capable of transferring data to a secure database* - *The myAirCoach system is capable of recoding the time data input*

Goal (Successful End Condition)	- *The researcher is able to provide participants with a system capable of recording clinically relevant data for use during a clinical study* - *The participant is able to navigate the system and complete all the required tasks*
Post-Conditions	- *None*
Involved Actors	- *Researchers* - *Research participants (often patients)*
Use Case Initiation	- *Researcher develops a protocol that includes the use of the myAirCoach system to collect data*
Main Flow	1. *Researcher configures myAirCoach system to enable the input of required data and relevant reminders* 2. *Participant receives reminders to complete measurements and take medications as per protocol* 3. *Research participant utilises the myAirCoach system to input required data* 4. *All data are recorded and time-stamped* 5. *Data are automatically transferred to a secure database* 6. *Researcher can access the data and used the analysis capabilities of the MyAirCoach system to study and reveal underlying patterns.*
Relationships with other Use Cases	
Specific Description	
Relevance to MyAirCoach WPs	*WP3, WP4*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local databases or transmitted outside the framework of the central myAirCoach system*
Environmental restrictions	- *No environmental restrictions.*
Quality of service indicators	- *Database is populated with research participant's data* - *Minimal missing data – less than with standard to workbook*
References (optional)	- *No references are noted.*
Notes (optional)	*NA*
UML Sequence Diagram	*The current UML diagram is similar to UC1.5 with the only difference that the data collected from patients will be used for research purposes instead of the direct support of patients.*

UC4.7 – Using the MyAirCoach system to better define distinct asthma phenotypes/endotypes and apply a precision medicine approach

Generic Description	
Use Case Name	*UC4.7 Using the myAirCoach system to better define distinct asthma phenotypes/endotypes and apply a Precision Medicine approach*
Version	*V1.0*
Authors	*ICL*
Last Update	*December 2015*
Brief Description	*By analysing the broad panel of functional inflammatory and clinical markers recorded by the myAirCoach system, researchers could better define distinct asthma endotypes and phenotypes. This would help in identifying well characterised clusters of patients who respond (or not) to a specific treatment and in adopting a Precision Medicine approach with a significant positive impact on the healthcare costs*
Assumptions & Pre-Conditions	- *The myAirCoach Analytics components are capable of recording functional, inflammatory and clinical parameters* - *The myAirCoach system is capable of transferring data to a secure database* - *Researchers are able to access database and run scripts to retrieve relevant data*
Goal (Successful End Condition)	- *Definition of asthma phenotypes and endotypes* - *Application of Precision Medicine*
Post-Conditions	*None*
Involved Actors	- *Researchers* - *Patients*
Use Case Initiation	*Researcher accesses the myAirCoach central database and analyse data*
Main Flow	1 *Patient using myAirCoach system agree to their anonymised data being used for research* 2 *Medication usage and clinically relevant data recorded and uploaded to central data base* 3 *Researcher accesses data base and retrieves the specific subsections of the data that are of his/her interest* 4 *Researcher is offered with analysis and visualisation functionalities that can help for the identification of important asthma patterns and support the understanding of asthma* 5 *Analysis capabilities of health records can be used for the*

	assessment of asthma related phenotypes/endotypes
Relationships with other Use Cases	
Specific Description	
Relevance to MyAirCoach WPs	*WP4,WP5*
Privacy & Regulation restrictions	*Patient data should not be copied or stored in any local database and transmitted outside the network of the myAirCoach system* *Patients should consent for their data to be used for this purpose*
Environmental restrictions	*None*
Quality of service indicators	*Researches are able to access and analyze patients' data*
References (optional)	*None*
Notes (optional)	*None*
UML Sequence Diagram	The UML diagram of the current use case is identical to the one provided in UC4.4. The two use cases are discriminated based on the types of analysis and visualisation that they are based upon.

4.2.2.3 **Community of asthma patients oriented use cases**

The current section describes use cases that include functionalities that will facilitate a myAirCoach community in supporting each other.

UC5.1 – Asthma community leader boars to promote healthy lifestyle

Generic Description	
Use Case Name	*UC 5.1. Asthma community leader boards to promote healthy lifestyle*
Version	*V1.0*
Authors	*UMAN*
Last Update	*December 2015*
Brief Description	*The myAirCoach system could use leaders boards to promote a healthy lifestyle and increase patient engagement. For example an*

	activity level (e.g., step counter) leader board could be integrated into the system, allowing for patients to compete with other users. This would engage users, and at the same time help promote a healthy lifestyle.
Assumptions & Pre-Conditions	- *User's activity levels can be monitored* - *The myAirCoach system is capable of transferring data to a secure database* - *myAirCoach system allows for patients to set-up leaderboards* - *User's activity data can be displayed on a leaderboard and automatically updated*
Goal (Successful End Condition)	- *Users are signed up to an activity level leaderboard and can track their progress against the myAirCoach community*
Post-Conditions	- *None*
Involved Actors	- *Patients*
Use Case Initiation	- *User signs up to the activity level leaderboard*
Main Flow	1. *User's activity levels are recorded* 2. *User's data is transferred to the myAirCoach database* 3. *A user signs-up/creates an activity level leader board on the MyAirCoach Virtual Community Platform* 4. *The user uploads his/her activity levels, messages regarding privacy preservation are presented.* 5. *Other user's join leader board* 6. *The activity levels of each user appear on the leaderboard* 7. *Leaderboards are updated automatically at regular intervals*
Relationships with other Use Cases	
Specific Description	
Relevance to MyAirCoach WPs	*WP5*
Privacy & Regulation restrictions	- *Patient data should not be stored to any local databases or transmitted outside the framework of the central myAirCoach system* - *Patients should consent to their activity data being presented on the leaderboard*
Environmental restrictions	- *None*
Quality of service indicators	- *Users engage with the leaderboard system*
References (optional)	- *None*

Notes (optional)	- *None*
UML Sequence Diagram	*No UML required this functionality will be supported by the online MyAirCoach virtual community. This functionality shouldn't be automated since it can introduce issues of privacy, and should always be based on direct user selection.*

4.2.3 Use Case Evaluation and Prioritisation

The above 24 use cases were prioritised via a two stage exercise. Stage one involved the segregation of use cases that would be achievable and measurable within the lifetime of the myAirCoach project from those that would not be. MyAirCoach partners were sent all use cases and asked to assign each use case to one of the two categories. Any use case that was felt to be unachievable was removed prior to stage two of the exercise. 12 partners voted, ensuring that use cases were assessed across all different areas of expertise (e.g. clinical, hardware, software etc.)

Table 4: Use case evaluation and prioritisation stage one

Use Case	Achievable	Not achievable
UC1.1 Using environmental measurements for the protection/ information of the user	12	0
UC1.2 Using the myAirCoach system to determine whether stepping up the current therapy or changing asthma medication really improves asthma control	10	2
UC1.3 Monitoring of asthma by patients to provide objective evidence of their condition to their healthcare team	12	0
UC1.4 Using the myAirCoach system to monitor asthma control and early detection of the disease worsening	12	0
UC1.5 The use of the myAirCoach system as an electronic version of a patient's asthma action plan	12	0
UC1.6 Using the myAirCoach system to monitor how regularly patients are taking (or not) their medication	12	0
UC1.7 Using the myAirCoach system to alert patients to improper inhaler technique	11	1
UC1.8 Using the myAirCoach system to monitor patients' physical activity and its impact on asthma control	12	0
UC2.1 Feedback of asthma state to family members or carers of patients with asthma	10	2
UC2.2 Using the myAirCoach system to support the parents in ensuring a proper compliance of treatment of their children	8	4
UC3.1 Creating and/ or providing modifications to the action plan of a patient	12	0
UC3.2 Using inhaler measurements to supervise the patients adherence to the prescribed action plan	12	0
UC3.3 A healthcare professional could access patient's	12	0

data in order to provide patient feedback remotely (i.e. over the phone or via email)		
UC3.4 Using the myAirCoach system could facilitate GPs to interact with specialists and increase their awareness of asthma diagnosis and management	8	4
UC3.5 Using the myAirCoach system as a platform for the effective follow-up of patients	12	0
UC3.6 Using the myAirCoach system to identify intra and inter-patient early predictive markers of asthma worsening and exacerbations	11	1
UC4.1 Setting up the system to run a simulation session	11	1
UC4.2 Running a simulation session and comparing the results	11	1
UC4.3 Predicting the patient's treatment progress via simulation	10	2
UC4.4 Using myAirCoach to determine medication effectiveness and the frequency of side-effects	11	1
UC4.5 Using the myAirCoach system to determine seasonal variation in airway inflammation and asthma control	10	2
UC4.6 Using the myAirCoach system to collect data for clinical trials	12	0
UC4.7 Using the myAirCoach system to better define distinct asthma phenotypes and apply a Precision Medicine approach	10	2
UC5.1 Asthma community leader boards to promote a healthy lifestyle	11	1

Following stage one, 11 use cases remained. Stage two involved the prioritisation of these use cases by 12 myAirCoach partners and 7 members of the advisory patient forum. Use cases were categorised as either high, medium or low priority in terms of their innovation and added value to end-users. These were converted into averaged scores using the formula: high = 3, medium = 2 and low = 1.

Table 5: Use case evaluation and prioritisation stage two

Use case	High	Medium	Low	Average Score
UC1.1 Using environmental measurements for the protection/ information of the user	**11**	**8**	**0**	**2.58**
UC1.3 Monitoring of asthma by patients to provide objective evidence of their condition to their healthcare team	**14**	**4**	**1**	**2.68**
UC1.4 Using the myAirCoach system to monitor asthma control and early detection of the disease worsening	**14**	**5**	**0**	**2.74**
UC1.5 The use of the myAirCoach system as an electronic version of a patient's asthma action plan	**12**	**6**	**1**	**2.58**

UC1.6 Using the myAirCoach system to monitor how regularly patients are taking (or not) their medication	**9**	**8**	**2**	**2.37**
UC1.8 Using the myAirCoach system to monitor patients' physical activity and its impact on asthma control	7	8	4	2.16
UC3.1 Creating and/ or providing modifications to the action plan of a patient	**12**	**4**	**1**	**2.37**
UC3.2 Using inhaler measurements to supervise the patients adherence to the prescribed action plan	8	8	1	2.16
UC3.3 A healthcare professional could access patient's data in order to provide patient feedback remotely (i.e. over the phone or via email)	7	8	2	2.05
UC3.5 Using the myAirCoach system as a platform for the effective follow-up of patients	6	10	1	2.05
UC4.6 Using the myAirCoach system to collect data for clinical trials	9	5	3	2.11

Use cases with a score of greater than 2.33 (highlighted in bold) were felt to be the most important and these should be measured during the evaluation in WP6.

4.3 Identification of specific goals for the MyAirCoach project

Based on the above results, the consortium underlined 6 cornerstone goals that were considered of great importance and are also feasible in the time frame of the project. In detail the following goals were separated:

- Use environmental measurements for the protection/ information of the user
- Ongoing monitoring of asthma to provide objective evidence of a person's condition to their healthcare team
- Use the myAirCoach system to monitor asthma control and enable early detection of the exacerbations
- Use the myAirCoach system to provide an electronic version of a patient's asthma action plan
- Use the myAirCoach system to monitor how regularly patients are taking (or not) their medication
- Use the myAirCoach system to create and/ or modify the action plan of a patient

4.4 Evaluation Protocols

The task of protocols' evaluation should be directly connected to the outputs of D8.5 *Ethics, Safety and mHealth Barriers (regulation, legislation, etc.)*, as it will comply with the plan proposed in this deliverable and will also contribute for updating the deliverable based on new privacy, safety and ethical needs that may arise in the timeline of the project.

All procedures will be carried out in agreement with the myAirCoach project's Ethics Manual. All relevant national and international European conventions (i.e. Helsinki Declaration) have been fully integrated in the manual. This will lead to the recognition of key ethical and legal issues and the development of a relevant project policy towards resolving these issues. In addition, it will specify which data are essential for the project and which should be excluded from retention. The manual will be also used to scan all project partners' deliverables and conduct. Furthermore, an experienced ethics supervisor, provided by Asthma UK, was established to act as the project Ethics Advisory Board. The role of the ethics supervisor will be to oversee all relevant issues and to train the participants on how to abide with the recommendations of the Ethics Manual. At last, the mHealth barriers for the adoption of myAirCoach solutions such as regulatory (security, medical devices, mHealth interfaces) and legislation frameworks, policy issues (patient empowerment, reimbursement) and GSMA (Policy and Regulation for Innovation in Mobile Health, 2012) will be monitored.

4.4.1 Ethics

All UK based medical research will receive ethical approval by a NHS Research Ethics Committee (REC). Similar regulations and ethical approvals will be required for research performed in other countries (i.e. Netherlands). The ethics committees will review applications for research and ensure that the requirements placed upon the participants are acceptable. They will also review all study documentation (e.g., patient information sheets, consent forms, surveys, etc.) to ensure that participants will receive sufficient information to help them decide whether they wish to participate in the research. Following ethical approval, research conducted in NHS organisations will need to obtain management permission (R&D approval), from the NHS organisations responsible for hosting the research.

4.4.2 Data Management

Data collected during this research will be handled with appropriate care and according standard operational procedures (SOPs). Participants' data will be anonymised. Subjects' initials and unique trial numbers will be used for identification. Transfer of data between devices will be done using encrypted storage devices only. Paper copies of consent forms, clinical research files and paper surveys will be stored securely in a locked cabinet at the associated host institutions. Electronic data will be stored in the myAirCoach network drive. Accesses to computers will be password protected. The study database will have additional password protection available only to the staff involved in the research. Study documentation will be archived and subject to audit for a minimum of 15 years, as required by good clinical practice. Transparency of data will

answer requirements of the EMA policy and clinical trial EU rules. More details about the data management plan can be found in the D7.6 deliverable.

4.4.3 Patient safety

To protect the rights, safety and wellbeing of research participants, written informed consent will be obtained by all included patients. Investigators will clearly explain the rationale for undertaking the research, how this will be conducted and which are the expected results. It will be stated that patients are under no obligation to consent and that consent will be carried out before undergoing any procedure. Potential participants will be allowed as long as they need to come to an informed decision. This may involve having time alone for reading the information sheet and/or questioning the research investigator. The right of the participants to refuse to enter or exit at any time the study, without giving reasons and without prejudicing further treatments, will be respected. A copy of the signed informed consent will be given to the participant, while the original will be retained at the study site.

5 MyAirCoach User Centred Design Methods

User Centred Design (UCD) is defined as the interactive approach of system development that focuses specifically on the system's usability and usefulness[39]. In this direction, the UCD methods are aiming to form a strong link between intended user groups and technology developers based on the continuous iteration of analysis, design and evaluation steps throughout the timeline of a project.

UCD is specifically important for the development of health oriented solutions as it can help not only for their usability but also for the preservation of the safety of patients and the protection of the privacy of their health record. It is therefore considered very important that the MyAirCoach project involves patients and their families as well as healthcare professionals, doctors and medical researchers in the design and implementation stages of the foreseen system.

Although, UCD can significantly increase the time of system development processes when compared with traditional methods, it can elevate some important difficulties in the decision-making process and provide direct goals for the developers. Furthermore, the final results of a project following a UCD process require fewer changes after the deployment of the system and as such contribute significantly to the long term reduction of development cost. Finally, the involvement of different types of user groups in the development process from the first stages of a project helps to build a sense of community and shared purpose, whereas it can significantly support the dissemination and exploitation purposes based on the introduction of the system to the participants of the feedback sessions.

There is no single recipe for success in user-centred design process, especially when considering the highly dynamic environment of system development. Often design processes of system components have to be parallel and the development of others may need to be finalised before the accurate definition of its specifications. Therefore, the purpose of the UCD methodology of the MyAirCoach is not to provide an detailed plan for future activities but to identify the areas of the project that could be benefited from the feedback of users and experts outside the consortium and propose some indicate methods that could be applied for this purposes

More specifically the UCD methodology of the MyAirCoach project is aiming to:

- Bring all partners to a shared understanding of the importance of UCD
- Starting a discussion among the consortium on how UCD could be incorporated into the project tasks (Based on sections 5.1 and 5.2)
- Support the deployment of UCD assessment methods by providing a reference manual for the most important methods that can be used (Section 5.3)
- Indicate some initial areas where UCD can be used and provide a number of examples for the related project tasks (Section 6)

5.1 Introduction

The User Centred Design (UCD) aims to support the development of all the MyAirCoach components, in every phase of their design and implementation and through the involvement of the targeted user groups[40,41]. This involvement is carried out by talking directly to the users, allowing them to test the functionalities offered by the MyAirCoach and therewith to test and confirm whether their needs are being met. The main goal of this process it to understand whether the proposed system can be easily and effectively used and whether it has a positive impact on the management of asthma disease both by doctors and also by the patients themselves[42,]. Furthermore, the UCD approaches aim to create hardware and software components that do not only fulfil the specified functional requirements, but are also introduce no risks to the safety and privacy of their users[43,44].

5.1.1 Human Centred Design Process for Interactive Systems

Human Centred Design is a methodology for the creation new solutions based on the requirements of users and the adaptation of the development processes based on the continuous user feedback and prototype evaluation[45].

Figure 33 shows the standard for "Human-Centred design processes for interactive systems" as defined by ISO 13407, and in relation to the MyAirCoach project objectives.

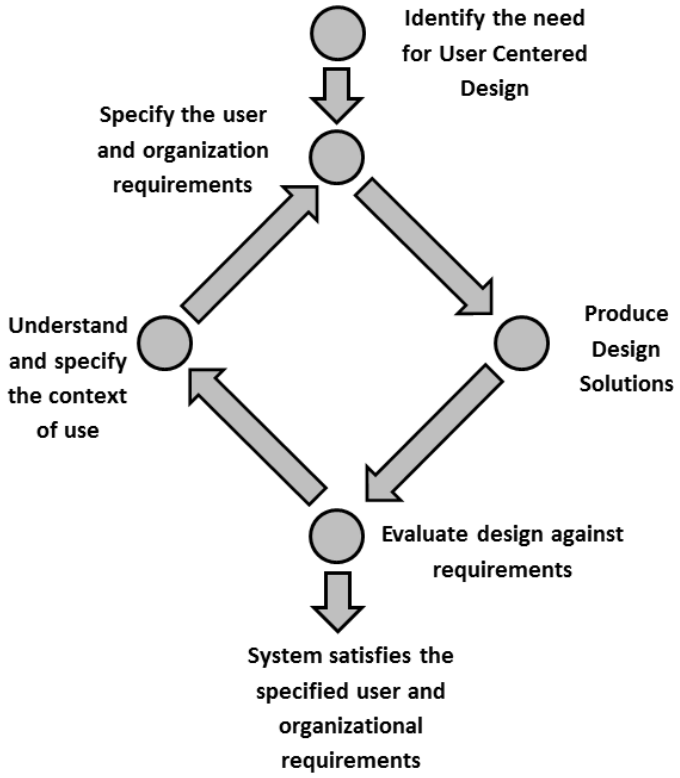


Figure 33: User Centred Design process for interactive systems[39,46]

According to the previous block diagram illustration, User Centred Design should be divided into six methodology steps:

Identify need for User Centred Design: Users are a fundamental element to take into consideration in the design and development process. In the case of medical applications the involvement of users in the design process becomes even more important due to the risks introduced by new technologies. Especially for the user group of asthma patients the myAirCoach system needs to take careful steps forward taking always into consideration the provided feedback and combining the results with the opinion of doctors and experienced healthcare providers.

Understand and specify the context of use: The knowledge of the specific context in which services and device will be used is crucial. Information related with the specific situations in which the systems is going to be used helps the designers and developers to outline the technical requirements of the final system. The outcome of this phase gathers the important characteristics during the use of all the components of the myAirCoach system.

Specify the user and organisational requirement: The current phase specifies in more detail the specific functionalities and deep technical issues, and may include:

- Required minimum duration of operation for the hardware devices.
- Required performance of the system components in situations of medical emergency.
- Usability of devices and software tools
- Relevant statutory or legislative requirements, including safety and privacy.
- Cooperation and communication between users and other relevant parties.
- Management of change, including training and personnel to be involved.
- Feasibility of operation and maintenance.
- Human-computer interface and workstation design.

Produce design solutions: The design solution is done considering all the information obtained in the previous phases, as well as that provided by the study of the state of the art and the experience of the project's consortium. This process takes into consideration the following elements:

- Development of a design proposal.
- Optimisation of the proposed solution.
- Presentation of the solution to the involved user groups
- Modifications to the design in response to the user feedback

Evaluate designs against requirements: Evaluation is not the final step in the design and development process. In UCD the evaluation is present in every step of the projects life cycle, limiting in this way the cost of changes at the final stage. The analysis of the acquired feedback from all involved users guaranties the continuous improvement of the design and the production of innovative solutions to problems and redefines the requirements of the final system as well. The responsibilities of this stage can be summarised as follows:

- Evaluate the system components functionalities
- Extract conclusions regarding extra needs, new requirements, usability test, etc.

- Repeat this process until human-centred design goals are met.
- Manage the iteration of design solutions.

System satisfies specified user and organisational requirements: When the evaluations are completed and the produced outcome satisfies all requirements and the defined goals are achieved, the myAirCoach system will reach its final form. The final evaluation results will be reported analytically, summarising the reached objectives, context, system functionalities and methods.

5.1.2 Waterfall Enhanced Model for Human Centred Design

By definition a waterfall model, is development process the steps of which are deployed based on a rigid downwards sequence like a waterfall and for which the maintenance and adaptation of the system to the dynamic set of specifications does not require the return to the initial definition of requirements. (see Figure 34).

Note: Although the current development framework is mainly used for the software components[47], it can be applied to the design of the MyAirCoach inhaler based sensor also, but with the main difference that after the finalisation of the hardware design and the development of the first prototype (D3.2 Final Design of the Hardware and embedded software) no changes will be applicable in this area and within the timeline of the project of the project. On the contrary, future commercial exploitation after the completion of the project would be highly useful, as it would be able to utilise the detailed analysis of the evaluation campaigns (WP6 MyAirCoach Evaluation)

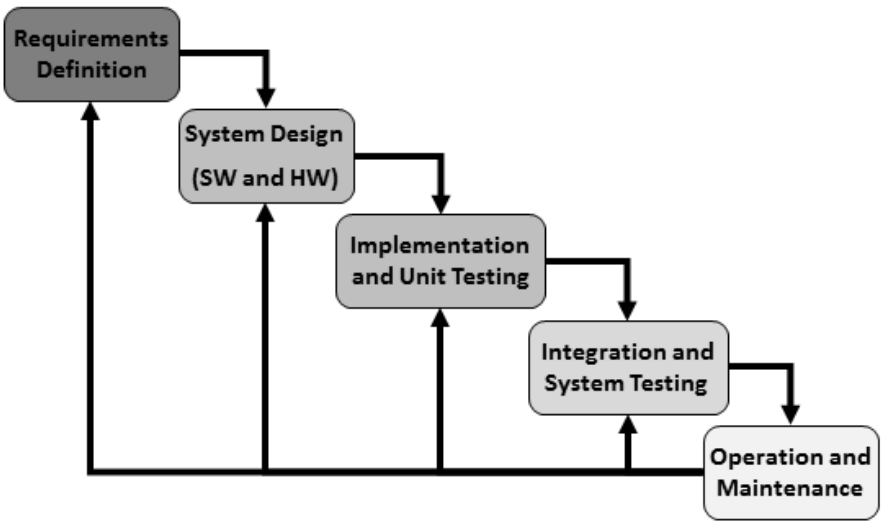


Figure 34: Waterfall model of system development[47]

Based on the desired characteristics of waterfall development model that include higher levels of adaptability and faster adaptation to the results of evaluation processes, an alternative approach of UCD process can be followed as shown in Figure 35.

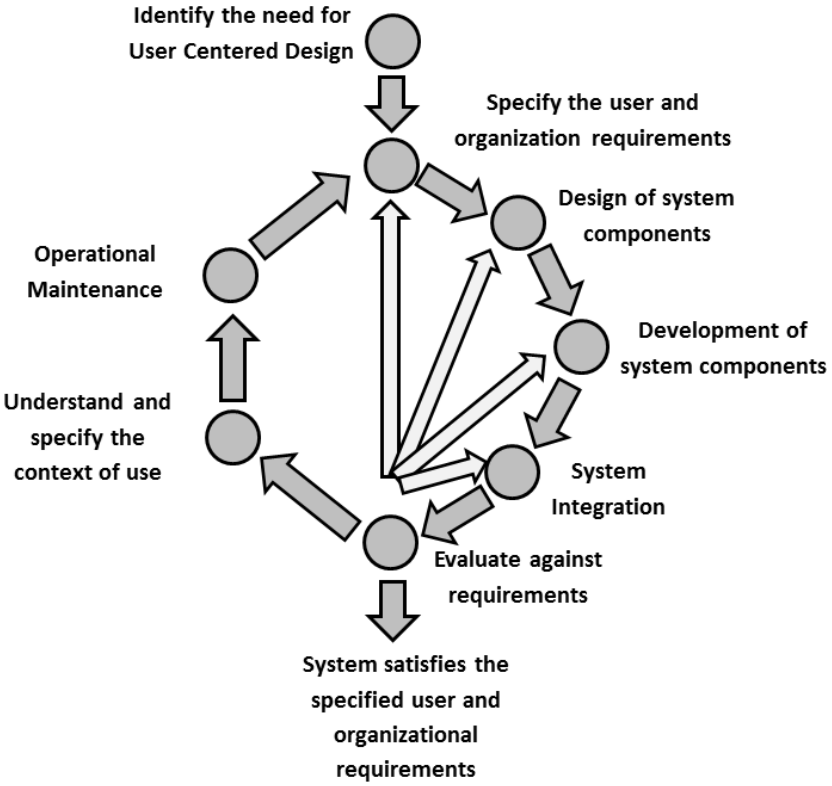


Figure 35: Waterfall enhanced model of User Centred Design process[48]

5.2 User Assessment methods towards User Centred Design

A variety of methodologies have been defined and used over the past that aim to the objective understanding of important aspects of user experience. The following sections provide and detailed but concise summary of the most important methodologies as they are related to the goals of the MyAirCoach project. In order to better describe their positioning in the different stages of development the reviewed methods have been separated into three main categories.

1. Methods for the assessment of user feedback (See following section 5.3)
2. Methods for user assisted design (See section 5.4)
3. Methods for user assisted implementation (See section 5.5)

It should be noted that all the above three categories are tools to be used for the User Centred Design Process of the MyAirCoach based on the specific requirements of tasks an towards the final implementation of the unified and integrated system for the support of asthma community.

5.3 Methods for User Feedback Assessment

The current section summarises the main characteristics of the most common methods for the collection of user feedback and describes their relevance to the objectives and the workplan of the MyAirCoach project. In this way the collected information is aiming to serve as a reference manual that will support for the selection of the appropriate assessment methodology for the understanding of user needs and requirements in all the phases of the project and in both planned tasks and unexpected issues.

5.3.1 Questionnaires

A questionnaire is a set of questions that are defined and sorted in order to allow the objective and accurate collection of user responses and their translation to useful and statistically significant information. Although questionnaires are less flexible than other methods of feedback collection such as interviews, the obtained data can be objectively analysed especially when open text answers are not included. Furthermore, the ease of deployment makes questionnaires a very cost effective method when it is required to reach a large number of participants especially when electronic and online platforms are used.

The preparation and deployment of questionnaires should follow some general phases that ensure the increased objectivity and accuracy of the final results.

1. **Definition of the questionnaire's objective**. This phase should always be the starting point of any questionnaire as it is highly connected with the final objectivity and accuracy of the results. Any changes in the objectives of a questionnaire should be documented and its preparation should be re-evaluated from this first step.
2. **Definition of the potential user groups and questionnaire participants**. It is essential to identify the user groups that should be included in the questionnaire deployment. Furthermore, the selection of participants is also a fundamental step in this process so as to allow the best representation of each user group and enhance the accuracy of the final results of the questionnaire. Once the user groups are identified prioritisation may be required when their relevance to the research objectives is different.
3. **Formation of the questionnaire**. In this step the objectives of the questionnaire are separated into specific parameters/information that should be assessed from the participants. Groups of questions can be defined in this step in order to make the questionnaire easier to understand by the participants and also increase their engagement (examples of categories can include personal data, asthma condition, medication adherence, inhaler technique, use of asthma apps, …)
4. **Deployment of the questionnaire**. In the framework of this step the questionnaire is distributed to the participants and the completed forms are collected by the responsible researcher. Furthermore, and for the case of

anonymised participation, this step should be planned so as protect the privacy of participants.

5. **Analysis of the results**. This step is the statistical annotation of the results and the separation of statistically significant outcomes. When designed properly the interpretation methodology of questionnaires should be defined in detail before the collection of responses so as to protect any analysis bias.

Summary Table
Type of Results
• Quantitative and Qualitative results
Main Objectives
• Information regarding some specific issues (e.g. knowledge about area, demographic data) with prefixed possible answers. • Prompt the participants by asking direct questions. • Definition of the minimum number of questions that can assess the required parameters without introducing bias to the answers of participants. • Methodology for the analysis of the results towards quantitative and qualitative results depending on the targeted area.
Advantages
• Appropriate technique for large samples (Large number of target users can be reached especially when an online questionnaire platform is used) • Objectivity in assessment and analysis (Depending on the proper definition of questions and the selection of representative groups of participants) • Systematic analysis possible presents a good relation information-cost • Much data can be acquired in short time • User facilities are provided concerning when and where to answer it • Online questionnaire platforms can be used for the simplification deployment and offer to the participants the option to answer in their home environment. • Anonymised participation can increase the truthfulness of answers. • Good relation of information cost especially when model electronic questionnaires can be used without jeopardising the accuracy of results.
Disadvantages
• Response rate is usually low unless the participants are engaged with the goals of the questionnaire and consider its goals to be highly important • Reliability of the answers is not very high unless the questionnaire is structured in such a way that can allow the detection of inconsistences in the answers of a participant and help their exclusion from the analysis • No personal contact with users, that can lead to reduced engagement • Less flexible than interviews, without the possibility of participants to deviate from the predefined sequence of questions

• The inhibition of participants to answering some questions cannot be assessed • Method should measure the variable that is intended to be measured • When online platforms are used users with reduced accessibility to internet or computers are marginalised
Recommendations
• The questions should be clear enough so that all participants can understand its content regardless of their age or education • The possible answers should be known in advance for most of the questions. Open text questions should be used only when new ideas or unexpected answers are considered possible. The quantitative analysis of other types of questions is considered more accurate and less influenced by interpretation bias • The questionnaires should be anonymous and the goals of the questionnaire should be described to the participants. In this way, participants are usually more engaged and are expected to answer more truthfully. • Carefully design the questionnaire for the minimum number of questions and expected time for completion. Too long questionnaires can cover a wider informational area but if participants lose their interest the final results will not hold adequate statistical significance. The optimum balance between the number of questions and the patience of participants should be investigated. • Open questions should be as specific as possible in order to direct the answers to the specific parameter and simplify the analysis phase • Vocabulary should be carefully selected and revised. Technical terms and unusual wording should be avoided when possible. • Inclusion of informative figures should be always considered. Figures can make the questionnaires much more interesting and easier to complete
Number of end users
• Min. 10 per area under investigation depending on number and the type of questions (multiple choice, open text, prioritisation, etc)
Cost
• Low especially when considering the possibility to use the same questionnaire in different stages of the project or when online questionnaire can be used without affecting the quality of results

Types and indicative examples of questions

1. **General questions:** These questions are used to establish the user profile and can include questions about the age, sex, residence etc.

Example
Gender: □Female □Male

2. **Open questions**: This type of questions is aiming to obtain subjective information and also to prompt participants to provide their suggestions or comments outside the rigid framework of question/answer

Example
Based on your experience with asthma disease, please provide in the following box your view on why the majority of asthma patients misuse their inhaled medication (number of uses and technique of use)

3. **Scalar questions**: These questions are intended to provide a quantitative measure of the targeted information

Example
Evaluate your inhaler technique ranging from "Bad-0: I don't know how to use my inhaler at all" to "Fair-5: I know how to use my inhaler but I usually make mistakes" and "Great-10: I know exactly how to use my inhaler and I always perform all the required steps without any mistakes"

Bad					Fair					Great
0	1	2	3	4	5	6	7	8	9	10

4. **Multiple choice questions**: For this type of questions the answers are separated into a small number of choice so as to facilitate the analysis of the results

Example
When using a Metered Dose Inhaler, how long after you start breathing in should you press/activate your inhaler?
□Before I start breathing in
□Exactly the same moment that I start breathing in
□A little after I start breathing in
□Approximately in the middle of my breath
□Just before I stop breathing in

5. **Ordered questions**: This type of questions are aiming to understand the priorities of uses in regards to their needs or validate their knowledge on a specific area

Example
Order the following functionalities that you would consider important for a mobile application that supports asthma management □Reminders for inhaler use □Indicators for increased pollution □Intuitive instructions for the proper use of medication □Communication with health care professionals □Sharing of my health status with my family

5.3.2 Interviews

The interview is a method to understand the unique point of view of a participant through the face-to-face interaction with an interviewer. The information provided by the interviews is mainly qualitative and should be carefully analysed by professionals in the field in order to underline measures of statistical value. Interviews provide a unique approach for the assessment of users' preferences and attitudes and can also allow the introduction of new ideas of suggestions by the participants themselves and thus they hold the promise of enhancing the innovation potential of a project. Interviews are considered very important for the extraction of requirements in order to understand an field or area of focus, and are also a useful tool for the design process since they can be used to assess in whet degree the user requirements are met by a system.

The preparation and deployment of interview should follow some general guidelines that ensure can increase the significance and the importance of the collected feedback.

1. By means of the prepared questions, the participants should be directed to share their experience about the field under study and avoid simplified answers. The selection of questions should be also done in such a way that will allow participants to answer truthfully to the interviewer. Unlike the questionnaires, the questions prepared can be modified during the interview and be adapted to the context.
2. The location to carry out the interviews can vary and should ideally be a neutral location that offers privacy, especially when sensitive medical data will be discussed. Interviews can be also scheduled to be done over the phone or through the internet, but always when such an option is not considered to reduce the level of trust between the participant and the interviewer.
3. The questions should be written down in advance and as a form of a discussion plant that can help the interviewer direct the interview in the

appropriate area and do not deviate from its main objective. The questions that will be asked to the user should follow a coherent plan and be separated into categories in order to help the participant understand them more easily and avoid any confusion of possible frustration

4. When appropriate interviewers may use recording devices in addition to their written notes in order collect a more detailed record of participant responses. It should be underlined that such an approach should be first approved by the responsible ethics committee and should not be used when the interview is aiming to assess sensitive private medical information of users.

Summary Table
Type of Results
• Qualitative results
Main Objectives
• Gather information from face to face sessions between participating users and interviewers • Allow a more open and free discussion away from a set of predefined questions • Allow the understanding of the participants point of view and support the sharing of ideas and suggestions from the side of the participant that may be adopted in the following steps of the project • Especially useful for the assessment of parameters and indicators that are difficult to express in writing
Advantages
• Users' preferences and attitudes can be obtained based on interactive discussions between participants and interviewers. • More detailed information can be gathered from the user than through questionnaires. Interviewer can ask for more details when an answer is not considered relevant or specific • Increased adaptability of questions to the context of discussion and the actual responses of participants. • Very effective for high level evaluations (e.g. getting information regarding the users' preferences, impressions and attitudes). • High response rate and reduction of elimination of irrelevant answer. The interviewer can clarify a question and be more specific when required. • Great reliability of the data collected. The interviewer can understand when the participant loses interest and starts answering without much thought • The user's real needs can be assessed based on the face-to-face communication • The user can be asked to provide ideas for new approaches and explain them easily and in detail to the interviewer.

- It is possible to solve user's doubts during the interview due to the direct relation between the interviewer and the user
- Very useful method for users with low educational level of physical restriction that cannot easily express their ideas in writing. Especially useful for children and older individuals.
- Useful method to find unexpected problems in the product development and get feedback in the form of suggestions.

Disadvantages

- Many economic and time resources are needed to carry out the interviews.
- Possible lack of objectivity and bias (e.g. interviewer affects the responses of participant, interviewee tries to please the interviewer and responds in favor of the suggested approach, the interviewee is not comfortable and provides untruthful answers)
- Difficult to apply to disperse populations, especially when different interviewers are required for different times in the course of the project (Reduced consistency of assessment)

Recommendations

- The total duration of an interview should not extent beyond one hour in order to maintain the interest of participants and allow their honest and truthful participation
- The quality of the information collected by an interview is directly connected with the quality of the selected questions. Define the interview questions as clear and direct as possible.
- The interview should be prepared in advance both in terms of content of questions and also their sequence and categorisation.
- During the interview the questions could be adapted to the needs of the interviewee and explanations should be given by the interviewer when needed
- Some additional questions can be added during the interview according to the users' answers and the flow of the discussion between the interviewer and the participant
- Possible answers should not be defined in advance and the participants should be allowed to express their views as unbiased as possible by the interviewers.
- When applicable and wherever possible, the location of the interview should be in an environment where the interviewee can use the proposed system.
- Interviews questions are not considered effective for the understanding of the user's experience during the use of the system. For this kind of feedback other methods are considered more appropriated such as the plain observation of the user during a testing session.
- If the interviews are going to be conducted by more than one person detailed introduction and interview methodology is considered very important in order to maintain the consistency across the interviews.
- Focus should be given to the personal experiences of the participants.

• Questions that lead the interviewee to a specific answer should be avoided. Any source of bias should be excluded from the expression of questions. • Simple Yes/No or multiple choice questions should be avoided since they do not use the full potential of interviews and can be easily accessed through questionnaires. • The questions should be asked independently and based on the selected sequence. Combination of questions in the time of the interview should be avoided since they will probably confuse the participant. • Testing and preparation interviews with a researcher outside of the responsible research group can be very useful both for the optimisation of interviews and the maintenance of consistency among different interviewers. • If the recording of the session is not conflicting with any ethical requirements, and after getting the approval of the participant, the interview can be recorded so that more information can be obtain later with a more careful study. The effect of recording on the responses of the participant should be also studied carefully since issues of reduced trust may arise.
Number of end users
• Approximately 5 to 7 participants
Cost
• Medium

5.3.3 Surveys

The main objective a user survey is to gather information related to the user's preferences and opinions rather than to collect feedback about a proposed system or device. In this way, surveys are aiming to collect quantitative data that the participants can provide irrespectively of the details of the specific project. Qualitative information can be also extracted from this method about the user habits or attitudes but it is usually avoided due to the difficulty in their analysis towards generalised conclusions. The surveys are mostly used to measure user satisfaction or to build or validate user models.

The preparation and deployment of surveys is very similar to methodology followed for questionnaires with the main differences stemming from the higher objectivity of questions in the case of surveys. From another point of view, questionnaires can be more generic and cover a much wider spectrum of information types, whereas surveys are more related to the user's preferences and can be used as a complementary method of interviews.

The planning of the survey should be based on the following pillar components:

1. Definition of the targeted users before you composition of the questions.
2. Identification the method that will be used to distribute the surveys based on the identification of the optimal characteristics for the specific application. If the target users are concentrated in a specific location the best choice could be the direct face-to-face distribution of questions and collection of feedback. However

if the target users are spread in different locations and surveys are mandatory in different stages of the project electronic surveys through the use of online platforms could be the best solution.

3. A careful study of the characteristics of the user groups will allow the identification of issues that may lead to the exclusion of an important percentage of the population (e.g. reduces access to modern communication technologies, reduced educational level, issues of accessibility and disabilities)
4. Careful selection of the time period that the survey will be deployed.
5. The design of the survey should include the conditions that will indicate its completion (e.g. time deadline of minimum number of participations)

Summary Table
Type of Results
• Quantitative results
Main Objectives
• Quantitative information regarding users' preferences, habits, attitudes, etc. • Complement the outcomes of interviews with quantitative data of a larger scale
Advantages
• Less biased when compared with interviews • Less tendency from participants to lie based on the higher protection of anonymity (especially for the case of online studies) • Objective measurement to support the qualitative data of interviews • Fast and easy to complete by the participants • Useful in describing the characteristics of a large population (larger samples feasible; conclusion of statistically significant results) • Possibility to distribute through modern communication channels (telephone calls, email, online survey platforms, etc) • Many questions can be asked about a given topic giving considerable flexibility to the analysis process especially due to the expected high number of participations Standardised questions make assessments more precise and consistent
Disadvantages
• Standardisation usually leads researchers to exclude questions that may be highly significant but for a very small percentage of users. • Large sample are mandatory and thus the possibility of useful conclusions heavily relies on the participation of users • Survey research as opposed to interviews cannot reveal the underlining context of the participant's responses
Recommendations
• The duration for the completion of a survey form should be approximately between 5 to 10 minutes in order to allow the collection of significantly high

number of inputs by users. • Questions should be written in a direct way so that they will lead to accurate answers. • Multiple-choice questions should be preferred since they are easier to evaluate and they can lead to significant results more easily • In order to access the opinions of the participants use multiple choice questions with a set range of choices (strongly agree, agree, neither agree nor disagree, disagree, strongly disagree). • A carefully study of the target users is useful for the appropriate selection of the optimum method to carry out the surveys (in person, by phone, using online tools…). • In order to increase participation, start every session with an estimate of the duration of the session. Number the questions in order to allow the participants to understand what percentage of the survey they completed. The surveys should be carried out until either a deadline or a minimum number of completed surveys. • The evaluator should not see the responses until after their completion by a number of participants or ideally after the full completion of the survey. • The survey should be previously reviewed and tested for proper execution before its distribution to the participants.
Number of end users
• Large scale of participants
Cost
• Low

5.3.4 Contextual Inquiry

Contextual inquiries are observation inside real work context and they are used in order to assess information from the real life environments of the representative users so as to better understand their needs and requirements. This method can be combined with other interviewing processes as their observation and preparation phase. Contextual inquiries are commonly used in the first phases of the design process as well as in the evaluation process of a system.

The successful deployment and proper use of a contextual inquiry should be based on a number of basic components. Firstly, the users should be informed regarding the whole process and their written consent should be obtained. Even if this step can be considered to introduce some bias in many cases it should never be neglected or not include a detailed description of the process. Secondly, the researchers should study carefully whether the inquiry will be based on active or passive observation.

More specifically in the case of active observations the researcher explains to the participant the assessment process and in addition teaches to the participant how to perform some tasks. This kind of observation could influence in how the participants really behaves. On the other hand, and for the case of passive observing, the researcher does not provide any type of education or training to the participant, informing him/her

only regarding the assessment process and for which purpose the collected data will be used.

Summary Table
Type of Results
• Qualitative results
Main Objectives
• Understanding users' needs, preferences for certain tools or real life problems by observing them in their everyday environment
Advantages
• Direct measurement of behaviour, no biased report of intentions or narratives • More valid, when compared with other approaches. Less prone to lies due to the deployment in the actual life environment of the participant.
Disadvantages
• The interpretation of the collected data towards the definition of system design requirements is usually difficult and requires experience and expertise from the side of the researchers • Requires long times of observations, especially when quantitative data of user behaviour are needed • Blind to cognitive parameters of user experience. The user is not asked for feedback and thus only his/her actions can be documented • The collected data are not easily generalised due to the usually reduced number of users and the increased bias between researchers and between assessments.
Recommendations
• Duration: several hours up to several days per user • The use of affinity diagrams is recommended for the understanding trends in the behaviour of participants. • In the case of reduced time availability, the active observation approach should be preferred since it can provide more information but may be the source of undesired bias in the collected data. • The informed consent of participants is of crucial importance and should be never omitted. • A session of contextual inquiry should last more than 2 hours and depending of the type of information needed a participant can be observed with repeated sessions for a number of days. • If the minimum time requirements of the assessment are not considered feasible interviews should be considered as an alternative • The participants usually adjust to the presence of the researcher after 15 minutes and therefore observations are advised after this time threshold. • The observer should turn off his cell phone or device that can remind to the participant of the assessment and disturb his/her actions.

• The interview process when required should be designed carefully in order to avoid the bias in the contextual inquiry results. The results of the interview should not be discussed with the participant in order to avoid bias. • When required, the interview should be as short as possible and should never last more than two hours.
Number of end users
• Approx. 3-5
Cost
• Medium

5.3.5 Focus Groups

A focus group is a type of discussion assessment where a moderator leads more than one participant through questions on a specific topic. Users are asked to share their opinions, thoughts and ideas about a specific subject and discus their views towards a conclusion that can express the majority of participants. Focus groups are often used as an input in the design process and provide non-statistical data.

As a first step the moderator should Introduce the topic of the discussion and explains the participants what is expecting to get out from this process. It is advised that the participants are informed about the process of their selections and how the collected data are going to be used. In the next step of the session the moderator should start addressing some questions to the participants in order to start the discussion process. It is important that in this stage all participants express their opinion and answer a question so that they are not excluded in the following phases of the discussion. The moderator should avoid expressing an opinion regarding the topic of the discussion in order to reduce the assessment bias and detailed notes should be kept for further analysis after the discussion.

Summary Table
Type of Results
• Qualitative results
Main Objectives
• Collect user requirements by means of an open discussion among a few users lead by a moderator • Users are asked to share their opinions, thoughts and ideas about a specific subject and reach a conclusion as a group
Advantages
• The moderator of the session can motivate the discussion and engage participants to reveal their opinion • New ideas and approaches about a topic can be underlined through group discussion which supports the cooperation of participants for the understanding of a topic

- Rather natural discussion that evolves a well-designed guide encourages group members to think about the specific topic in more detail and provide their accurate feedback and truthful opinion.

Disadvantages

- Evaluation of the gathered is rather complicated and cannot be easily conform with a standardised input framework
- It is possible to assess the groups reaction to specific system components but the personal opinion of the participants cannot be assessed or assumed based on the results
- Focus groups do not produce reliable data on topics that are connected with strong feelings or deep beliefs, whereas discussions based on the sharing of private information, such as health data, cannot lead to significant results.
- No generalisations of the results are possible especially when the product/system that is discussed is intended for personal or private use.
- Not objective since the opinions expressed by participants are biased by the presence of other users.
- The moderator needs to be experienced in this type of discussions and support all participants to express their opinion, even if they consider that it is not popular among the others.

Recommendations

- The duration of each focus group sessions should be approximately 1-2 hours.
- The experienced moderator plays a fundamental role for the assessment of significant conclusions for the discussion.
- The list of desired topics should be prepared in advance and described with high level of detail in order to help the moderator to lead the discussion.
- The preparation of questions for a focus group should follow the same methodology as in the preparation of interviews.
- It usually advised that the initial questions of a focus group are easy to understand and answer by all participants in order to avoid the exclusion of a participant from the start of the discussion.
- Questions that intend to lead the participants to think new approaches and express their ideas are very useful and should be always included in a focus group session.
- Assigning time blocks for each topic and adjusting the schedule only when it is considered important will allow the discussion to cover all intended topics.
- The use of nametags is advised especially for large grouped so each one can be addressed by his name.
- The discussion should begin with an introduction to the objectives of the discussion and the use of the collected data.
- It is important devote some time on confidentiality and privacy issues and get the consent of all participants
- The moderator should not express opinions but only direct the discussion in the intended area of focus.
- Questions by the moderator should be repeated when addressed to a different participant in order to achieve their best possible understanding.

• When a change in the topic is required the moderator should clearly indicate this transition and introduce the next area of discussion. • Before the session starts and after the introduction the moderator should ask the participants for questions and clarify any issues of concern •
Number of end users
• Approx. 6-12
Cost
• Medium

5.3.6 Task Analysis

Task analysis is aiming to assess the cognitive actions and processes that are required by the user in order to perform a specific task. This method is essential when it is required to analyse in detail the user actions, and is particularly useful for the design of decision support systems as they are foreseen by MyAirCoach.

There are two main methodologies that can be applied within the task analysis method. One option is the use of the hierarchical task analysis where tasks or high level are decomposed in simpler ones, detailing the components and the sequences among them. The alternative option is the use of a flow chart, using which a sequence of actions from the user's point of view is presenting associating inputs and outputs.

Three are the main pillar components of the task analysis of users

1. **Understanding of Triggers:** What leads a user to perform a specific action?
2. **Understanding of Use Cases:** How the user performs an action or task and which are the main steps of his/her thought processes?
3. **Understanding of Goals:** Why the user performs an action, and which are the underlying intentions?

Summary Table
Type of Results
• Qualitative results
Main Objectives
• This method aims to better understand the actions of users and more specifically the cognitive processes that lead them to these actions.
Advantages
• Can reveal new information that is exploitable in the software design
Disadvantages
• Can be highly time consuming. • Requires the observation of expert users while completing the identified tasks • Observations of expert users obtain the risk to increased bias and difficulties in the generalisation process.
Recommendations
• This method should be used when your target users as well as the tasks to be

performed can be accurately defined. • Special focus should be given on the main functionalities of the system under development. • The definition of different workflows can lead to better and well-rounded results • Complex use cases should be avoided. It should be preferred to define additional simple use cases instead of complicating existing ones. • Graphical outcomes of task analysis should be preferred since they are more useful for the development process and easier to understand by the participants. • The description of use cases should be done with common language and specialised terms should be avoided.
Number of end users
• A minimum of 5 expert users is required for the collection of adequate information that can lead to significant results.
Cost
• Low - Medium

5.4 Methods for User Assisted Design

The current section summarises the main characteristics of the most commonly used methods for the involvement of patients in the design process of devices and software components. In contrast, to the methods for the collection of general feedback (see section 5.3), the current type of assessment focuses on the understanding of the opinions and suggestions of participants to specific design decisions as they will be used to form the actual final product.

5.4.1 Participatory Design

During a session of participatory design participants are encouraged to be directly involved in the design process of a specific application while the process and final outcomes are documented in detail by the researcher. The users are asked to cooperate for the design of a prototype using different approaches and following different goals as they are set by the researcher. Afterwards the initial prototype can be refined by the designers using more traditional processes. This type of method can be deployed in the first stages of system design and can also serve as a tool for the refinement of a system and after its initial development.

Summary Table
Type of Results
• Qualitative results
Main Objectives

- Involvement of users in the design process of an application so as to reveal their needs and requirements and also provide an alternative approach to the system developers

Advantages

- Better understanding of final users' needs and the functionalities that need to integrated with the final system
- Opportunity for users to influence the system's design process
- Opportunity for software developers to get suggestions and original outside views of the system
- Increase users' acceptance of the final system through the inclusion of the user community in the design process
- Relatively easy deployment of the method with reduced requirements for scheduling and planning of the session.

Disadvantages

- Requirements for extensive user involvement may lead to increased costs
- Relatively time intense and greatly influenced by the genuine participation of users. High risk of low engagement by participants leading to common results.
- Difficulty to gather users of special groups, especially when educational and health reasons do not allow the easy participation in the design process (e.g. elderly user or your kids that may use the system)
- Increased effort by designers to understand the perspective of users and their suggestions and translate them into technologies that should be developed

Recommendations

- The duration of a session should be between 1 to 2 hours in order to maintain the genuine interest of users and allow the completion of fundamental design tasks
- The preparation of a workshop related to the system to be developed is considered beneficiary for the purposes of participatory design.
- Due to its participatory nature of this type of assessment, interactive elements for users are considered very useful tool for the increased engagement of participants.
- A detailed record of each session could be proven very useful for later analysis or results and the understanding of the steps that lead the participants to the specific design
- The participants should be carefully selected and separated into groups for the optimal results of each session.
- A moderator may be required in some cases, and especially for the participatory design of complicated systems, in order to direct and help user reach the design goals of each session.

Number of end users

- Approximately 3-5 users should participate in a session.

Cost

• High

5.4.2 Co-Discovery

Co-discovery is a type of usability testing where two participants attempt to perform tasks together while being observed. The advantage of this method over the thinking aloud protocol is three-fold:

- The participants are encouraged to cooperate and exchange opinions in support of the designated purpose of the session
- The interaction between the two participants can bring out more insights than a single participant vocalising his or her thoughts
- This type of sessions are closer to the real use of the system in the users environment where help an suggestions may be available from other people in their environment.

This technique can be used during any phase of design and development but is specifically useful for the understanding of the usability of developed system prototypes, and should lead to adaptation and additions when necessary.

Summary Table
Type of Results
• Qualitative results
Main Objectives
• Observe a pair of participants performing tasks together and gain insights for the usability of the system and the proper changes in its design and offered functionalities
Advantages
• Detailed information on usability taking into account the cooperation of users • Fast and easy approach for the understanding of the system characteristics and the planning of future modifications • Rather natural style of interaction between users resembling real life help • Particularly fitted for applications of cooperation and interaction of participants in the framework of the proposed system.
Disadvantages
• Can lead to discomfort among the participants if the rules and goals of cooperation are not clear enough and not directly connected with the system's functionalities • Analysis of the collected data is relatively difficult due to their qualitative nature and inability to define the cooperation framework in fear of bias. • Inter-individual differences: One participants might dominate and overpower the others and the session
Recommendations

• An appropriate usability test method for the task under investigation for the specified number of participants should be defined that can be take into account the level of their cooperation. • The number of participants needs to be carefully selected depending on the usability method to be applied and should not extend to more that 4 for each session. • A clear evaluation goal needs to be defined • Rules for the conversation between participants should be defined at the beginning without reaching to very high levels of detail that may lead to confusion or even frustration of users.
Number of end users
• Usually 2 participants are involved in session, whereas in some cases they can be increased to a maximum of 4 .
Cost
• Low

5.4.3 Prototyping

Prototyping is the method for the collection of user feedback based on a prototype version that is produced during the initial stages of development. This technique is particularly useful as a feedback mechanism that can directly affect the development tasks with specialised comments on specific components of the system. The prototype used in this type of assessment can a functional version of the actual system or even a conceptual description that summarises the intended functionalities. However, the closer to the used prototype is to the actual foreseen system, the better quality of results and feedback should be expected.

A number of different approaches and prototyping methodologies can be adopted in this type of user involvement. The following list summarises some of the most important and commonly used concepts.

- **Rapid Prototyping:** In this type of design methodology, draft prototypes are quickly develops incorporating new designs which are directly evaluated and rejected or form the basis of other draft prototypes based on the results.
- **Reusable Prototyping or Evolutionary Prototyping:** In this type of design approach efforts are made for the construction of a prototype that is gradually evolves to the final design based on the feedback of users and developers.
- **Modular Prototyping or Incremental Prototyping:** In this case, new parts are added on as the design cycle progresses enhancing the capabilities of the final system.
- Horizontal Prototyping**:** In this methodology the prototype covers a large breadth of features and functions even if most of them are not completely relevant or have overlapping functionalities. As the design process progresses the prototype is refined as ad features are modified for the optimum final product.
- Vertical Prototyping**:** In this type of design the proposed prototype covers only a narrow slice of features and functions which form a specialised solution

covering only a percentage of the intended functionalities of the final system. As the design process progresses the separate prototypes are combined towards the formation of the final system.

- Low-fidelity Prototyping**:** In this case prototype is plainly describes with text and informative figures that summarise not only the interfaces but also the system capabilities.
- High-fidelity Prototyping**:** prototype is implemented so as to be as close to the actual design as possible in terms of look and feel, interaction, and timing.

Summary Table
Type of Results
• Model of a system or product
Main Objectives
• To test a prototype of the system and support its optimisation based on the actual needs and requirements of users and before the finalisation of the development processes.
Advantages
• Allows the accurate identification of usability problems and can support the analysis of the causes behind this issues in an early stage of the design or development process • Allows the test of different and specific aspects of the intended final system • Helps users understand the idea and concept of the final system and thereby increases user involvement • Provides a methodology for fast evaluation and feedback collection from users during the design and development cycles.
Disadvantages
• System development is significantly slower as user feedback usually lead to changes in the design and development components • The repetitive implementation of prototypes increases the overall cost of development, both in terms of financial expenses and working time directed to tasks that may not be utilised in the final product • Prototypes can be the source of confusion for the participants, as they are presented in an incomplete and draft form • Prototypes allow only a partial analysis for the final product or system
Recommendations
• Prototyping is most beneficial in systems for which the user interfaces play a very important role in the overall system quality • The prototype presented to participants should not be modifies during the session so as to avoid confusion among the users and allow the accurate documentation of their comments for specific functionalities

• The history of prototype development should be documented in detail so as to allow a careful study be the developers and the utilisation of characteristics of different prototypes when considered appropriate. • Prototyping is very effective in the analysis and design of web applications and smartphone applications, based on the relative ease of high fidelity prototyping and the easy sharing with users. • Prototyping in highly recommended for iterative design process.
Number of end users
• Approximately 3-7 participants for every session
Cost
• Low – High (depends on kind of prototype)

5.4.4 Storyboarding

Storyboarding is a method for the collection of user feedback that is used to assess the optimal sequence between individual displays and actions within a system. It is based on the use of images demonstrating an interactive sequence that represent the behaviour of the system. Users are then asked to order the images so they describe a useful and easy-to-use interface. The storyboarding method provides real information about the structure and the scope of the application to be tested and it can be used for the collection of new perspectives for the design of a system and also for validating of a finalised design.

Summary Table
Type of Results
• Qualitative results
Main Objectives
• Validation of a design through sequencing of visual representations of episodes and sequences within the system interaction.
Advantages
• Relatively simple to design and very cheap to implement • Users can evaluate specific use case sequences focusing on specific components ot the system. • Useful for applications with a complex structure of information through the validation of separate and relatively simple usage scenarios.
Disadvantages
• It can introduce some difficulties in the design and process of the procedure depending on the type of system to be evaluated and the simplicity of the foreseen interfaces.
Recommendations
• Represent sequences of high-level scenarios in order to avoid the distraction of the users, and allow the easy understanding of the full process.

• It is highly recommended that participants are familiarised with the context of use for the intended system in general and the specific scenario in particular. • The collection of initial feedback from technology experts can provide useful suggestions for the optimisation of the storyboarding process towards more specific functional requirements. • The selection of users should be done carefully based on their knowledge level in the specific domain.
Number of end users
• Approximately 5 to 7 users should participate in the process for best results.
Cost
• Low

5.4.5 Card Sorting

One of the main problems of system designers and developers is related to the organisation and presentation of the information so that it can be easily understood by the users. The card sorting method is used in order to provide a solution in this issue on the basis of the actual user preferences. Card sorting consists from number of descriptions of concepts separated (cards) that the participants are asked to categorise according to their characteristics or relations. Once the cards are sorted, users should name each one of the separated groups of concepts and provide a short description of its discriminating characteristics.

Card sorting can be used in combination with low-fidelity prototyping for the acquisition of a more detailed view of the perspective of users.

Summary Table
Type of Results
• Quantitative results
Main Objectives
• Sorting of concepts by users and naming of each resulting groups to express their common characteristics • Discover the optimal organisation of the information within the system based on the actual needs of users.
Advantages
• Relatively simple to design and very cheap to implement • Usable early in the design process Useful to categorise information. It enables designers and developers to understand how target users group the items • Identifies terms that are likely to be misunderstood and/or difficult to categorise
Disadvantages
• It can introduce some difficulties in the design and process of the procedure

depending on the type of system to be evaluated and the simplicity of the foreseen interfaces.
Recommendations
• This method can be used in conjunction with paper prototyping for the better assessment and analysis of user perspectives. • The concepts to categorise should be as close as possible to the system components for the higher levels of output significance. • No additional instructions should be given to the participants, except from that the categorisation of cards should be based on their characteristics and similarities. • Define the context of each card as clear as possible in order to avoid misconceptions and confusions. • Deploy more than 7 sessions in order to get significant results. • The detailed explanation of the purpose of card sorting is expected to increase the involvement and effort of participants, and as such should not be omitted. • Participants should be prompt to explain the main reasons behind their categorisation • All cards should be categorised in each session • Researchers can select not to supervise the whole process in case the privacy of participants is expected to produce more accurate results. • A short and informative introduction to the card sorting process is advised so as to avoid misunderstandings about the card sorting itself. • An easier example of card sorting can be used as a fast and simple training of participants before the actual session. • Special attention should be paid to the selection of representative user group of participants. • Adequate time should be given to each session to allow the categorisation of all cards • Cards should be give to participants in a random order.
Number of end users
• Approximately 5 to 7 users should be involved in every session.
Cost
• Low

5.5 Methods for User Assisted Implementation

The current section summarises the main characteristics of the most commonly used methods for the involvement of patients in the implementation of devices and the development of software components. In contrast, to the methods of user assisted design (see section 5.4), the current type of assessment focuses on the involvement of the participants in the actual development processes and aims to increase their understanding regarding the development problems and barriers that can affect possible design decisions.

5.5.1 Expert Review

This method is used to collect feedback and specific suggestions from experts based on their experience in the implementation of similar solutions. In this way, expert reviews can increase the probability to identify the main problems and future risk factors for the development processes, and can be used for the compliance of the project with the best implementation practices used in the area of focus.

During each session, the expert is asked to use the system and evaluate both its functional and non-functional characteristics. The participant is also asked to identify possible flaws and suggest possible solutions or mitigation strategies based on his/her previous experience.

Summary Table
Type of Results
• Qualitative results
Main Objectives
• Evaluation of a system by expert reviewers and based on their previous experience in the field • Collection of suggestions and mitigation strategies for the improvement of the system and the addressing of identified risks.
Advantages
• Can be used to understand and resolve issues that cannot be identified by system users • Collects valuable input for the optimisation of design and development processes based on the best implementation strategies
Disadvantages
• Constrained by the experts knowledge regarding asthma • Not sufficient if not combined with other assessment methods that involve actual system users (in the case of MyAirCoach people in the asthma community)
Recommendations
• Include more than one experts who ideally have a different area of expertise • A detailed introduction to the objectives of the system will not only allow its accurate evaluation by may lead to useful suggestions by the experts for the extension of the intended functionalities. • Recording or documenting each session in detail can help for the analysis of the results in later stages. In the case of expert review the ethical requirements can be reduced since no sensitive and private information will be assessed.
Number of end users
• No end users are involved in this type of assessment.

• Approximately 3 to 5 experts should be involved for good results.
Cost
• Low

5.5.2 Usability Testing

Usability tests aim at evaluating an application based on the collection of data during the use of the system by actual users and optimally in the intended real world environment. During each session the participant is asked to perform a series of tasks by using the system components that need to be evaluated. During the same time the researcher is documenting the complete process and tries to identify usability problems. Furthermore quantitative data can be assessed such as the time needed to perform each task or user's satisfaction with the application.

The quality of the produced results of usability testing is connected to six important elements:

1. Detailed definition of the test objectives.
2. Use of a representative sample of end users
3. Representation of the actual real world environment of use
4. Accurate observation of end users and detailed documentation of the session
5. Collection of quantitative and qualitative indicators of usability
6. Collection of user recommendation for the improvement of usability

Summary Table
Type of Results
• Qualitative results
Main Objectives
• Improve of the usability of a product based on the completion of real task and ideally in the real world environment • Enable developers to collect qualitative and quantitative data related to the requirements of both functional and non-functional system requirements
Advantages
• A small number of users is sufficient to identify numerous real life issues of usability, easily and in a short time period
Disadvantages
• Increased observation bias. The user responds differently than in the real life situations since because of the continuous observation by researchers. • Difficult and time consuming in terms of planning and analysis • Cannot cover a large number of interface issues • In many cases it is not possible to deploy in real life environments, leading to the assessment in the confined and controlled environment of a laboratory. • Not easily generalisable, depending on the capabilities of the specific user and

the action that was selected by the researchers for evaluations
Recommendations
• Increased number of participant can significantly improve the quality of results • Speaking out loud could help evaluators understand user's actions (see section regarding Think Aloud Protocol, section **Error! Reference source not found.**) • One user should be involved in each session • Two researchers are advised for each session so as to allow the uninterrupted documentation of the session and the interaction with the user when necessary
Number of end users
• A minimum number of 10 participants will allow usable results
Cost
• High

5.5.3 Heuristic Evaluation

This type of assessment methodology focusses on the understanding of usability issues of a system, based on the input of a small group of expert evaluators with experience in Human Computer Interaction. The measures that are used in this process are called heuristics and they summarise important aspects and qualities of interfaces.

The first step of towards the heuristic evaluation should be the definition of the system's interaction flow and the accurate description of the intended scope of the session. As the following step the evaluators can focus their analysis on specific interaction elements and provide their feedback, recommendations and concerns. Finally and after the evaluation is completed the group of all the evaluators should discuss the results of their analysis. The results of this method will be a list of comments related to the specific usability principles that have been selected (heuristics)

Summary Table
Type of Results
• Qualitative results
Main Objectives
• Usability evaluation by a small group of experts in Human Computer Interaction based on a set of well-defined heuristics
Advantages
• Accurate method for the identification of usability issues and concerns • Collection of feedback from experienced users of computer systems (different points of view, better understanding of the concept of usability)
Disadvantages
• Constrained to a small number of evaluators which makes difficult the understanding of the preferences of the intended user groups • Not sufficient for the understanding of usability, unless it is combined with other assessment methodologies that focus on the actual users

Number of end users
• No end users; Approx. 3-5 usability domain experts
Cost
• Low

5.5.4 Think Aloud Protocol

Thinking Aloud protocol is a technique used during usability testing, during which the participants are asked to describe their thinking process verbally in order to reveal their thoughts, feelings and opinions while interacting with system under evaluation.

Summary Table
Type of Results
• Qualitative results
Main Objectives
• Vocalise thoughts, feelings and opinions during the evaluation of the system
Advantages
• Access to relation between actions, thoughts and feelings • Direct observation of behaviour in relation to the preferences of the participant • The method might help some participants to concentrate on the intended tasks and use the system more efficiently
Disadvantages
• Increased observation bias since the participants will avoid expressing verbally their dissatisfaction with an element of the system • Slower use of the system due to the constant explanation of actions • Use case is very different to the real life use of the system • Increased attention levels will decrease the frequency of errors as they would be observed in real life situations • Additional training in order for the participant to understand the protocol
Recommendations
• The duration of each session should be between 2 and 3 hours in order to allow the collection of adequate information without becoming tiring for the participants • Encourage the users to comment liberally on their actions, intentions and thoughts. • The minimum amount of help and support should be provided to the participants by the researchers. In this way the results of the analysis will be indicative of the usability of components to new users • The preparation of a notes template to be used by the researcher can help significantly the assessment process and provide a structure for the collection of

data that will facilitate also the following analysis process.
Number of end users
• Approximately 5 to 7 participants are required for the collection of adequate feedback and lead to useful conclusions
Cost
• Low- Medium

5.5.5 Performance Measurements

Performance measurements are specific types of usability tests that focus and assess quantitative metrics. Some examples may include the time the user needs to perform an action, the number of steps needed to find a specific section in the system, etc. Often and on the basis of these metrics specific goals are defined that are used to characterise the quality of the system. An indicative example can that all users should be able to register and login the system.

Summary Table
Type of Results
• Quantitative results
Main Objectives
• Test whether the system reaches the predefined levels of performance
Advantages
• Allow the objective measurement of effectiveness and efficiency
Disadvantages
• User satisfaction can't be assessed with this method but only the usability of system components • Should be always combined with a number of qualitative methods in order to allow the overall understanding of the users experience
Recommendations
• Log file analysis could be very useful to evaluate technical features of the system. • The collection of as many different types of information as possible will allow the more detailed evaluation of the system, • Can also be used for the understanding of functional problems that may be visible in later trial stages.
Number of end users
• Approximately 3 to 7 participants are required for reliable results
Cost
• Low

5.5.6 Log File Analysis

The current method is based on the automatic storing of user-system interactions and their subsequent analysis for the identification of usage patterns as well as potential problems in usability. Although the current method is producing reliable quantitative data their analysis for the extraction of usability indicators is sometimes difficult to formulate. An example of log file analysis can be the automatic documentation of failed login attempts in order to reveal the simplicity of the specific functionality. This example is also considered relatively difficult to interpret since a percentage of failed login attempts can be caused be malicious software instead of actual user difficulties.

Summary Table
Type of Results
• Quantitative results
Main Objectives
• To identify usage patterns as well as potential problems of usability through the automatic logging of related actions.
Advantages
• Provides a historical trace of the systems use • Easy way to gather large amounts of data on user behavior without having to recruit users or design the deployment of assessments. • Completely transparent to the user, with minor effects on the system's performance
Disadvantages
• Log files cannot assess the intentions of users when performing an action of the reasons behind an error. • Log files cannot be easily interpreted for the understanding of usability issues, since in many case unrecognised sources of noise can be present.
Recommendations
Number of end users
• Ideally a large scale of users based on the popularity of the system and the reduced conflicts with ethical requirements.
Cost
• Low

5.5.7 Feature/ Consistency/ Standards Inspection

Feature inspections are used to analyze specific characteristics of a system and they are usually based on use case scenarios. One indicative example is the ability to login and use the private area of the MyAirCoach system.

Consistency inspections are based on the same methodological approach but they are used to validate the consistency between multiple products developed under the same

project. In the case of MyAirCoach consistency inspections can be used for the comparison of the web based platform with the mobile application.

Finally standards inspections are used to reveal the compliance of the final system with universally accepted standards that may cover areas such as security, communication, usability etc.

Summary Table
Type of Results
• Qualitative and Quantitative results
Main Objectives
• Analysis of fundamental system characteristics based on use case scenarios and through the use of accurately defined measured
Advantages
• Analysis of certain features and functionalities of the system in a well-documented and accurate manner. • Necessary to guarantee the consistency of the features used in similar systems • Standardised approach for the evaluation of a system • Unbiased evaluation based on the definition of use case scenarios
Disadvantages
• Expert knowledge required in the area of interest for the definition and deployment of assessment and analysis procedures • Checklist of features should be as well rounded and extended as possible • No information collected for the designers or the developers point of view • Only useful for common systems or applications where features can be compared to standards
Recommendations
• Special attention and effort should be dedicated to the design of the protocol. The deployment of the actual evaluation for all three types of inspections is significantly lower. • The success of feature/consistency/standards inspection depends mainly on the proper selection of parameters that cover the full spectrum of system functionalities and characteristics. • The most effective approach to defining the checklists of parameters to assess is to start from the principal functions and continue with their segmentation to simpler concepts. • Feature and consistency checklists should be standardised in the context of evaluation.
Number of end users
• No end users involved in all three types of inspections • A minimum number of 1 to 3 designers is advised for significant results

Cost
• Low

5.6 Overview of Methods for UCD

The following table summarises the most important characteristics of the above described methods of user involvement in the system development processes.

Table 6: Summary of User Centred Design approaches

	Important Characteristics of User Centred Design Methods			**User Centred Design Components**		
UCD Methods	**Type of Results ***	**Number of End Users , Experts or Designers**	**Cost****	**Assessment of User Feedback**	**User Assisted Design**	**User Assisted Implementation**
Questionnaire	**QL,QT**	**Min 10**	**L**	✓	✓	✓
Interviews	**QL**	**≈5-7**	**M**	✓	✓	✓
Survey	**QT**	**Large Scale**	**L**	✓		
Focus Groups	**QL**	**≈6-12**	**M**	✓		
Contextual Inquiry	**QL**	**≈3-5**	**M**	✓		
Task Analysis	**QL**	**Min 5**	**L-M**	✓		
Participatory Design	**QL**	**≈3-5**	**H**		✓	
Co-Discovery Method	**QL**	**≈2-4**	**L**		✓	
Prototyping	**M**	**≈3-7**	**L-H**		✓	
Storyboarding	**QL**	**≈5-7**	**L**		✓	
Card Sorting	**QT**	**≈5-7**	**L**		✓	
Expert Review	**QL**	**≈3-5 Exp.**	**L**			✓
Heuristic Evaluation	**QL**	**≈3-5 Exp.**	**L**			✓
Usability Test	**QL**	**Min 10**	**H**			✓
Thinking Aloud Protocol	**QL**	**≈5-7**	**L-M**			✓
Performance Measurements	**QT**	**≈3-7**	**L**			✓
Log-file Analysis	**QT**	**Large Scale**	**L**			✓
Standards Inspection	**QL,QT**	**≈1-3 Des**	**L**			✓
Feature Inspection	**QL,QT**	**≈1-3 Des**	**L**			✓
Consistency Inspection	**QL,QT**	**≈1-3 Des**	**L**			✓
*** (Qualitative: QL, Quantitative: QT, Model of System or Product: M)**						
****(Low: L. Medium: M, High: H)**						

6 UCD methodology for the MyAirCoach

As already mentioned in the previous section the current UCD methodology is not intended to form a detailed plan for the future deployment of the project tasks, rather than to describe the main pillars of UCD to be followed and indicate some representative examples for the application of UCD for the specific tasks and work packages of the MyAirCoach project.

6.1 Hierarchy of requirements

An important component of the development of an innovative system is the understanding and balance between the desired characteristics of the final product. In this regards an issues of fundamental importance is the formation of a hierarchy that should be used as the foundation upon which all design and development decisions will be made. For the case of MyAirCoach, and in general for applications of medical use, the requirements for utility should always be based upon the preservation of high standards of ethical requirements and the safety of system users.

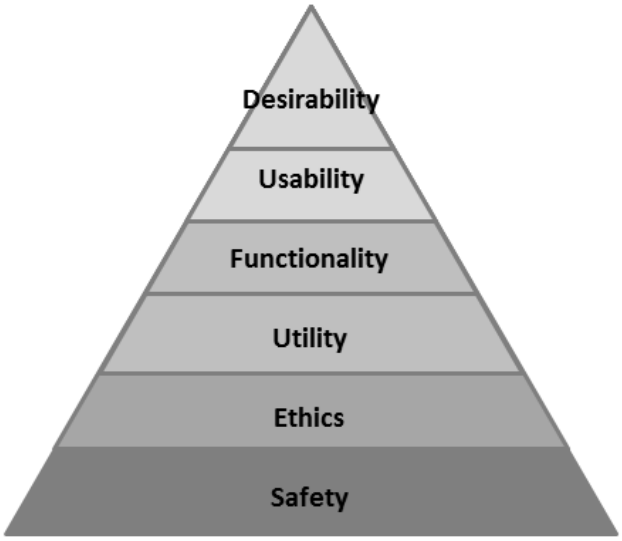


Figure 36: Hierarchy of requirements for the MyAirCoach project

6.2 Participants of the MyAirCoach UCD Process

The MyAirCoach UCD process is intended to involve all the different types of users targeted by the project objectives and also collect the feedback from experts in the medical field, technology developers and commercial entities in order to support the different tasks of the project. In detail the following groups can be involved in the UCD processes:

Patients: The MyAirCoach project is primarily aiming to enhance position of asthma patients in the healthcare process and provide them with an innovative set of tools that support self-management approaches. It is therefore of fundamental importance to take into consideration of the patients' perspective and adapt the design and implementation processes of the MyAirCoach project in order to address issues or requirements indicated by the patient community

Families of patients: In many cases the family of patients plays an important role in the effective management of their disease and the safe treatment of asthma attacks. In this direction, the feedback from family members of patients can provide important insights and useful suggestions on how they can effectively and efficiently help their loved ones.

Doctors and Caregivers: Apart from functionalities supporting healthcare professionals during their daily activities and helping them supervise the current condition of their patients the MyAirCoach project is aiming to help towards the understanding of asthma in a personalised basis. The involvement of both doctors and patients will help in this direction and increase the usability and accuracy of the proposed Decision Support System.

Researchers: Researchers in the fields of bioinformatics and medical modeling could be involved in order to provide crucial feedback for the identification of areas that hold the promise of high clinical significance and support the development of signal processing and modelling functionalities that can be used for the clinical research of asthma and the increased understanding of the parameters and risk factors that affect the condition of patients.

Commercial Organisations: The involvement of commercial entities will help towards the identification of the project's outcomes that hold the promise for viable product ideas.

Technology developers: The consultation with technology developers outside the project consortium is expected to support the standardisation of the produced system and help for the identification of alternative technological approaches towards the compliance with best practices.

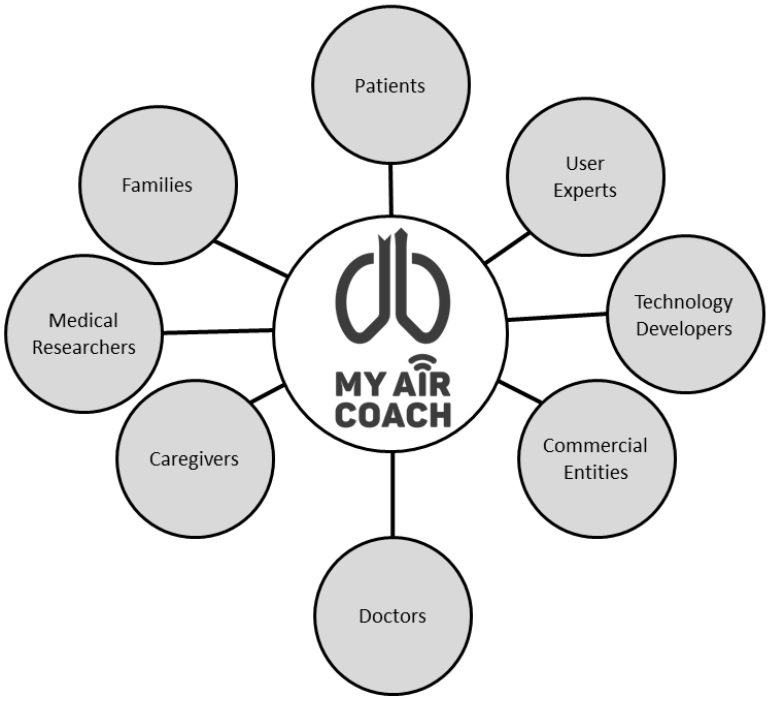


Figure 37: User groups involved in the MyAirCoach UCD processes

6.3 *Planning of UCD in the framework of MyAirCoach*

Table 7 gives a broad overview over UCD methods planned to be applied within the different WPs of the MyAirCoach design and development process.

Table 7: Overview of UCD methods planned to be applied within the different WPs.

		User Centred Design Components		
WP	Title	Assessment of User Feedback	User Assisted Design	User Assisted Implementation
WP1	User Needs, System Requirements, Architecture		✓	
WP2	Test Campaigns, Measurements, Clinical Analysis	✓		
WP3	Smart Sensor-Based Inhaler Prototype and Wireless BAN Sensor Network	✓		
WP4	Computational Models, Intelligent Information Processing and DSS Module	✓		✓
WP5	Integration and Personalised Guidance System		✓	✓
WP6	Evaluation	✓		
WP7	Dissemination and Exploitation	✓		
Wp8	Management and Ethics	✓		

Table 8 provides a summary of the possible UCD methods that can be used for the specific tasks of MyAirCoach. This proposed plan is only an initial suggestion that should be revisited and modified throughout the project and on the basis of the actual needs of the project. In this way, the MyAirCoach project is aiming to be directly connected with all the targeted user groups towards the best possible results in terms of usability, usefulness and protection of ethical requirements and patients' rights. Furthermore the proposed plan is aiming to involve selected user groups to the implementation processes of the system which is expected to contribute for the collection of more valuable feedback.

Table 8: Suggested UCD evaluation methods for the myAirCoach Tasks

Task N°	Assessment type	User groups involved	UCD and evaluation methods applied
T1.2	Assessment of User Feedback	- Patients - Doctors - Researchers	- Questionnaire - Survey
T1.4	User Assisted Design	- Technology developers	- Questionnaire - Focus Group
T2.2	Assessment of User Feedback	- Patients - Families - Doctors	- Questionnaire - Contextual Inquiry - Survey - Focus Group
T2.3	Assessment of User Feedback	- Patients - Families - Doctors	- Task Analysis - Questionnaire - Contextual Inquiry - Survey - Focus Group
T3.1	User Assisted Implementation	- Patients - Doctors	- Usability - Standards Inspection - Feature Inspection
T3.2	User Assisted Implementation	- Patients - Doctors	-
T3.3	User Assisted Implementation	- Patients - Doctors	-
T3.4	User Assisted Design	- Patients - Families - Doctors	- Questionnaire - Prototyping - Co-Discovery
T4.2	User Assisted Implementation	- Patients - Doctors - Researchers	- Expert Review - Heuristic Evaluation
T4.3	User Assisted Implementation	- Doctors - Researchers	- Expert Review
T4.4	User Assisted Implementation	- Patients - Doctors	- Expert Review - Heuristic Evaluation

		- Researchers	
T4.5	User Assisted Implementation	- Patients - Doctors	- Usability Test - Performance Measurement - Think Aloud Protocol - Log Files Analysis
T5.1	User Assisted Design	- Patients - Families - Doctors	- Prototyping - Participatory design - Think Aloud - Story Boarding
5.2	User Assisted Design	- Patients - Families - Doctors	- Prototyping - Participatory design - Think Aloud - Story Boarding - Card Sorting
T5.3	Assessment of User Feedback	- Patients - Families - Doctors	- Questionnaire - Survey - Focus Group
T5.4	User Assisted Implementation	- Patients - Doctors - Experts	- Usability - Performance Measurements - Expert Review
T6.1	Assessment of User Feedback	- Patients - Researchers	- Prototyping - Participatory design - Story Boarding
T6.2	Assessment of User Feedback	- Patients - Doctors	- Questionnaire
T6.3	Assessment of User Feedback	- Patients	- Questionnaire
T6.4	Assessment of User Feedback	- Patients	- Questionnaire
T6.5	Assessment of User Feedback	- Patients	- Questionnaire
T7.1	Assessment of User Feedback	- Patients	- Questionnaire
T7.2	Assessment of User	- Patients	- Questionnaire

	Feedback	- Healthcare commercial entities	- Task analysis - Focus groups
T7.3	Assessment of User Feedback	- Patients - Healthcare commercial entities	- Questionnaire - Task analysis - Focus groups
T7.4	Assessment of User Feedback	- Patients - Healthcare commercial entities	- Questionnaire - Task analysis - Focus groups
T8.3	Assessment of User Feedback	- Patients	- Questionnaire

6.4 MyAirCoach methodology for User Feedback Assessment

The first pillar of the User Centred Design approach of the MyAirCoach project is the creation of the plan for the assessment of user feedback in support of the project activities and for the re-adaptation of the selected approaches towards better results. In this direction the MyAirCoach project is aiming to involve all the targeted user groups (asthma patients and their families, healthcare professionals and medical researchers) in order to allow:

- The determination of the user requirements from the MyAirCoach system (WP1/T1.2)
- The efficient deployment of the project's test campaigns (WP2)
- The support of the activities related to the design and development of all system components (WP3, WP4, WP5)
- The optimal evaluation of the produced system towards accurate results (WP6)
- The support of dissemination and exploitation activities based on the opinion of asthma community and experts from commercial entities
- Understanding of the concerns of participants regarding ethical and safety issues towards the proper adaptation of the project's guidelines in this areas (WP8)

T1.2	User requirements, clinical procedures and MyAirCoach use cases	AUK

Methodology

The basic purpose of the current task is to underline the user requirements for the MyAirCoach system, and direct the design and development of its components towards more useful and usable functionalities. Therefore the involvement of the targeted user groups is considered fundamental for the best results of this process and the optimum overall design of the MyAirCoach system.

Involvement of users

- Patients: Patient involvement will reveal the most important functionalities that should be implemented for the system to be adopted as a reliable tool for asthma self-management
- Doctor: The involvement of doctors will reveal the most important decision support functionalities that can help them in their medical practice
- Researchers: The collection of feedback from researchers can support the design and development of the computational modelling, intelligent information processing and decision support modules of the system.

Evaluation method

The possible methodologies that can be used for the collection of user requirements may include:

- Questionnaires for the detailed understanding of the user requirements and suggestion of new functionalities. Especially useful for doctors and medical

researchers
- Surveys for the easy assessment of patient feedback regarding their requirements and opinions regarding the MyAirCoach functionalities

T2.2	Clinical Monitoring of Patient with Asthma	UMAN

Methodology

A fundamental component of the test campaigns of the MyAirCoach project is the monitoring of important clinical parameters that will not only allow the accurate modelling of asthma patients bur will also form an informational basis that will be used by researchers for the understanding of asthma disease.

In this direction the feedback from users can provide valuable insights for their understanding of asthma disease that may be overlooked by the researchers. For example the feedback of patients regarding the allergens that they consider dangerous for the triggering of asthma attacks can indicate areas of clinical significance that could be further analysed by researchers. Another example could be the feedback from doctors, regarding their evaluation regarding the adherence of different types of inhalers, how it affects the health condition of their patients and what they consider the optimum strategy in addressing these issues (medication, inhaler type, action plan, communication, training, etc.)

Involvement of users

- Patients: Patient involvement can reveal areas that hold the possibility of high clinical significant
- Families of patients: The families of patients can provide a more objective evaluation of the clinical condition of the patient
- Doctor: The involvement of doctors will provide a more accurate image of the healthcare practice and the actual barriers of different prescriptions and inhale devices

Evaluation method

The evaluation methods in this task should be compatible with the actual clinical monitoring as foreseen by the task, some of the possible methodologies can include:

- Questionnaires for the detailed understanding of the doctor's experience
- Contextual inquiry of the condition in the healthcare environment (In this case increased focus should be given to the ethical and privacy requirements)
- Surveys for the easy assessment of patient feedback in the clinical sites
- Focus groups that involve doctors and patients can offer insights to their communication and difficulties in expression of their perspectives to one another

T2.3	Dietary, nutritional and environmental screenings	UMAN

Methodology

The second component of the MyAirCoach test campaigns will focus on the dietary, nutritional habits as well as the environmental conditions that affect the asthma condition of patients. In this way, the MyAirCoach project is aiming to shed light on asthma disease from a different perspective and allow the multi-parametric understanding of the mechanisms underlying its progression.

In this direction the feedback of patients can provide useful feedback on how the weather and the pollution in their environment affect their health status. Furthermore patients can indicate types of food products that they consider to help them manage their disease of trigger adverse effects. All this information may reveal patterns of behaviours and characteristics that could be further investigated by researchers. Doctors can also provide very useful feedback summaries of their conclusions regarding the environmental conditions and how they affect the number of visits by asthma patients.

Involved User Groups

- Patients: Patient involvement can reveal areas that hold the possibility of high clinical significant regarding the effects of weather, pollution and nutrition on their asthma state
- Families of patients: The families of patients can provide a more objective evaluation of the clinical condition of the patient and also verify the opinion of the patients.
- Doctor: The involvement of doctors will provide a more accurate image of the effects of weather and pollution on asthma based on the relative number of patients experiencing an attack and arranging a visit.

Evaluation

The evaluation methods in this task should be compatible with the actual clinical monitoring as foreseen by the task, some of the possible methodologies can include:

- Task analysis for the detailed understanding of the user's methodology regarding how they prepare when they consider that either weather or pollution increase the risk of them having an asthma attack.
- Questionnaires for the detailed understanding of the doctor's experience
- Contextual inquiry of the condition in the healthcare environment (In this case increased focus should be given to the ethical and privacy requirements)
- Surveys for the easy assessment of patient feedback in the clinical sites
- Focus groups that involve doctors and patients can offer insights to their communication and difficulties in expression of their perspectives to one another

T5.3	Security and privacy subsystem	CNET

Methodology

The health oriented nature of the MyAirCoach project, and especially the collection of

sensitive medical data for the decision support of patients and doctors, creates the requirement for increased levels of security. The purpose of the current task is to develop the needed functionalities that will protect the privacy of patients and the confidentiality between patients and doctors. Furthermore and within the same framework any related risks will be addressed with increased priority and whenever they occur in the timeline of the project.

The involvement of users for the support of the current task is considered of fundamental importance as it will reveal the opinion of patients and doctors and allow the understanding of their concerns regarding the security of their sensitive information. Furthermore, and as the project progresses the feedback of users will indicate whether the increase of the system functionalities is related to privacy concerns and investigate possible strategies to better inform the users about the high levels of data security within the MyAirCoach system.

Involved User Groups

- Patients: Collecting the opinion of patients will indicate the components of the system that can be optimised for addressing their concerns on privacy.
- Families of patients: The families of patients increase the collected feedback and help for the better understanding of the user's experience regarding privacy.
- Doctor: The involvement of doctors will help the developers understand the confidentiality needs of healthcare professionals and design the system components for the optimum protection of medical and personal data.

Evaluation

The possible methodologies that can be used for the assessment of the opinion of users regarding data security include:

- Questionnaires for the detailed understanding of the doctors' perspectives on the protection of confidentiality
- Surveys for the easy assessment of patient feedback regarding the use of electronic health systems in general and the envisioned MyAirCoach system in particular
- Focus groups that involve doctors and patients can offer insights to their concerns regarding the communication capabilities within the MyAirCoach platform

T6.2	Operational planning and assessment protocol	UMAN

Methodology

The current task is aiming to define the assessment protocol that will form the basis for the evaluation of the MyAirCoach system in the final stages of the project. In this direction the protocol should allow the objective and accurate assessment of the system which is highly related to the engagement of participants, their genuine interest to the objectives of the evaluation process and the truthfulness of their responses. Therefore the operational planning and assessment protocols can be greatly benefited by a small number of trials that will indicate the optimum time length of the trials and

the correction of any parts that can be the cause of confusion.

Involved User Groups

- Patients: The collection of feedback from patients regarding the proposed protocol can lead to corrections that will increase the engagement of the patient user group in the evaluation process.
- Doctors: The involvement of doctors will support the overall design of the evaluation processes and help to increase the significance of the results of the evaluation process.

Evaluation

The possible methodologies that can be used for the assessment of the opinion of users regarding assessment protocol include:

- Questionnaires for the detailed understanding of the perspectives of doctors and patients regarding the deployment of the evaluation procedures, with special focus on their time length and sources of confusion.

T6.3	**Trial operation in semi-controlled environments**	**LUMC**
T6.4	**Field trials with patients**	**ICL, LUMC**
T6.5	**MyAirCoach evaluation of users' acceptance and socio-economic impact**	**LUMC**

Methodology

The above tasks are related to the actual deployment of the trials which will span throughout the third and last year of the project. In this respect user involvement can be used for the correction of possible difficulties in the deployment process and allow the fast and effective assessment and accurate analysis of the results of the evaluation processes

Involved User Groups

- Patients, Families, Doctors, Researchers: The collection of feedback from all involved users regarding the deployment process can lead to increased efficiency and correct any sources of confusion or delays

Evaluation

The possible methodologies that can be used for the assessment of the opinion of users regarding the deployment of the evaluation and analysis processes include:

- Questionnaires for the detailed understanding of the perspectives of doctors and patients regarding the deployment of the evaluation procedures, with special focus on their time length and sources of confusion.

T7.1	**Dissemination activities, materials and publication policies**	**EFA**

Methodology

The purpose of this task is to organise the dissemination activities of the project towards the most effective publication of the project results and the increase of the interest of the entire asthma community in the project. In this direction, a small number of assessments for the visibility of the project can provide help for the planning of new events and publications.

Involved User Groups

- Patients, Families, Doctors, Researchers: The collection of feedback from all involved users regarding the dissemination of the project is considered important especially when related with the commercial viability of the project outcomes

Evaluation

The possible methodologies that can be used for the assessment of the opinion of users regarding the deployment of the evaluation and analysis processes include:

- Questionnaires for the detailed understanding of the reach of the dissemination strategies in the asthma community (patients and their families, healthcare professionals and medical researchers)
- Questionnaire for the collection of opinions from MyAirCoach users and project participants for the improvement of publication strategy and the better preparation of dissemination material

T7.2	**Exploitation of the MyAirCoach business models**	**AEROCRINE**
T7.3	**IPR management**	**EFA, Allertec**
T7.4	**Standardisation and concertation actions**	**CERTH**

Methodology

The purpose of the above tasks is to organise the exploitation strategy of the MyAirCoach project and support the transformation of its research outcomes into viable commercial products. In this direction the opinions of users will help towards the selection of the MyAirCoach components that are most useful for the effective management of asthma. Furthermore, the collection of input from experts in the commercial environment will help to understand the commercial value of the MyAirCoach outcomes and protect the intellectual property generated within the project.

Involved User Groups

- Patients, Families, Doctors, Researchers: The collection of feedback from all involved users regarding the dissemination of the project is considered important especially when related with the commercial viability of the project outcomes
- Healthcare commercial entities: Commercial entities in the healthcare

environment can provide crucial feedback for the design of business models within the MyAirCoach project and toward the exploitation of its most important outcomes and results.

Evaluation

The possible methodologies that can be used for the assessment of the opinion of users regarding the exploitation of the project results include:

- Questionnaires for the detailed understanding of the importance of the project outcomes in clinical practice and the effective self-management of asthma disease
- Task analysis for the understanding of the effect of the MyAirCoach system in the quality of life of patients
- Questionnaire for the collection of feedback from commercial entities regarding all aspects of product commercialisation and the detection of the project outcomes that hold the higher commercial value
- Focus groups with market experts for the detection of commercialisation opportunities

T8.3	Ethical, safety and mHealth barriers issues	AUK, CERTH

Methodology

The participation of patients during the full length of the project together with the health oriented nature of the MyAirCoach system requires the creation and continuous adaptation of an ethical and patient safety manual. It is therefore evident, how important is the involvement of the group of patients in this process, as they can provide their suggestions for addressing ethical requirements and also indicate areas of concern that the project should focus on.

Involved User Groups

- Patients, Families, Doctors, Researchers: The collection of feedback from all involved users regarding ethical and safety requirements will allow the successful protection of participating patients and will support safe use of the final MyAirCoach system.

Evaluation

- Questionnaires for the detailed understanding ethical and safety concerns of all user groups and especially paints. Collection of suggestions for mitigation strategies.

6.5 MyAirCoach Methodology for User Assisted Design

The second pillar of the User Centred Design approach of the MyAirCoach project is the creation of the plan for the assessment of user feedback for the design of the system components so that they are based on the actual needs of users from their starting point.. In this direction the MyAirCoach project is aiming to involve all the targeted user groups (asthma patients and their families, healthcare professionals and medical researchers) in order to allow:

- The design of the end-to-end architecture of the system that will support the self-management of asthma by patients and the decision support of healthcare professionals (WP1/T1.4)
- The support of the design activities of all system components (hardware and software) (WP3, WP4, WP5)
- Design of the evaluation tools to be used within the project timeline (WP6/T6.1)

T1.4	Architecture and System Specifications	CERTH

Methodology

The purpose of this task is to define the overall architecture of the MyAirCoach system so as to facilitate the development of its individual components in the respective tasks and work packages. Furthermore, another purpose of the current task is to define the interconnections between the system components and allow the productive cooperation of the project partners for the development of the integrated MyAirCoach system.

In this direction the involvement of the technology developers from all related partners will help to determine the technical specifications of the system and address them in the system's architecture. Furthermore, as the project progresses the involvement of users can help for the inclusion of additional functionalities which should be translated to technical requirements.

Although, this process is not directly connected with the actual intended users of the system (patients and their families, doctors and medical researchers) it was decided to be included in the UCD methodology of the project due to the similarity of its methodological approach with UCD and its strong connection with T1.2.

Involved User Groups

- Technology developers: The inclusion of all technical partners in this process will allow the collection of a wide range of requirements that will cover all the desired characteristics of the system.

Evaluation

The possible methodologies that can be used under the current task for the assessment of the opinion of users include:

- Questionnaires/Requirement templates
- Focus groups/Discussions

T3.4	Testing, evaluation and production of the smart sensor-based inhaler prototype and wireless BAN network	IHP

Methodology

The current task is responsible for the testing and evaluation of the smart sensor based inhaler and the formation of the BAN network. Although, in this stage of the project the design and development of the device will be finalised the feedback by users can support non-functional issues like the look and feel of the device and how it is going to be attached on the inhaler. Furthermore, healthcare professionals can provide their opinion regarding the type of material to be used for the casing of the device and how to present the instructions for the use of the device to doctors and patients.

Involved User Groups

- Patients: Patient involvement is expected to reveal issues of usability and support the design of the casing of the device for better appearance and easy use.
- Families of patients: The families of patients of younger age can indicate issues of usability that can help them with the use of inhalers.
- Doctors: The involvement of doctors will provide design guidelines that are strongly connected to medical practice and should focus on health related issues of usability such as the antibacterial nature of the casing of the device

Evaluation

The possible methodologies that can be used under the current task for the assessment of the opinion of users include:

- Questionnaires for the detailed understanding of the doctor's opinion on the design and materials of the casing of the device
- Prototyping for the assessment of the issues of usability related to the form, feel and appearance of the device
- Co-Discovery an Think Aloud Protocols can be used as alternatives to the prototyping in order to allow participants to discuss their opinions or share their thoughts more effectively during the session

T5.1	MyAirCoach Personal Guidance and Support Application	MV

Methodology

The current task is responsible for the design and the development of the personal guidance and support application of the MyAirCoach project and as such it will cover the majority of patient and doctor user interfaces. More specifically, the targeted application will offer decision support capabilities to patients and their doctors and will also support the exchange of messages between them. Furthermore the system will allow the collection of subjective data by patients in order to assess parameters related to their asthma condition, and will include the MyAirCoach virtual guidance agent.

In this direction, user involvement will play a very important role in the design process

of the application as it is expected to form the basis for its increased usability, the intuitive presentation of health indicators, and the increased engagement of patients for the optimal self-management of their disease.

Involved User Groups

- Patients: Patient involvement is expected to reveal issues of usability and support the design of the application for optimal user experience and the informative visualisation of health parameters.
- Families of patients: The design of the MyAirCoach application can be greatly benefitted from the feedback of the families of patients, who will offer an additional perspective for the overall usability of the system.
- Doctor: The community of doctors can help for the understanding of the best design of the system interfaces from the clinical point of view. Furthermore, the input of healthcare professionals will allow the detection of misleading of unclear descriptions of medical concepts and their appropriate correction.

Evaluation

The possible methodologies that can be used under the current task for the assessment of the opinion of users include:

- Prototyping for the assessment of the issues of usability related to the structure and positioning of user interface components on the screen
- Participatory design and Co-Discovery for the active involvement of users in the design process and the collection of new ideas and approaches based on the experience of users with the management of asthma
- Thinking Aloud Protocol can be used in order to reveal the thinking process of the users and better understand the reasons behind their actions and choices when using the MyAirCoach personal guidance and support application.
- Story Boarding and Card Sorting can help for to define the system interaction sequences and group the provided functionalities for the better understanding and optimal use.

T5.2	Asthma related mHealth 2.0 virtual community	CNET

Methodology

The current task will be responsible for the creation of an online platform that will allow the discussion of asthma related issues in a safe and anonymised environment, so that patients can share their experiences and help others in the same position. Furthermore, the foreseen virtual community will operate under the supervision of healthcare professionals who will guarantee the misleading and harmful perceptions are not shared within the online community.

It is evident from the above that the proper function of the MyAirCoach virtual community platform is based on the proper use by the users and their increased levels of engagement. Therefore, the inclusion of the user community in the design processes under the current task is considered very important towards the overall objectives of

the task.

Involved User Groups

- Patients: Patient involvement is expected to reveal issues of usability and support the design of the virtual community platform for optimal user experience and increased engagement
- Families of patients: The design of the MyAirCoach virtual community can be greatly benefitted from the feedback of the families of patients, who will offer an additional perspective for the overall usability of the system.
- Doctor: The community of doctors can help for the understanding of the best design of the system interfaces from the clinical point of view so as to allow the sharing of useful experience and always in relation to asthma.

Evaluation

The possible methodologies that can be used under the current task include:

- Prototyping for the assessment of the issues of usability related to the structure of forum topics and the presentation of newly added comments
- Participatory design and Co-Discovery for the active involvement of users in the design process and the collection of new ideas and approaches for the effective sharing of their experiences regarding the management of asthma
- Thinking Aloud Protocol can be used in order to reveal the thinking process of the users and better understand their thought when browsing through the virtual community platform and participating in online discussions.
- Story Boarding can help for to define the system interaction sequences and how the topics of discussions are presented
- Cart sorting for the categorisation of discussion topics for the easy and fast accessibility of information by the virtual community members

T6.1	Creation of the MyAirCoach consultative patient forum	EFA

Methodology

The purpose of the current task is to form and maintain a functioning consultative patient forum that will support the UCD processes as they are described in the proposed in detail in the current section. A crucial component in this direction is the creation of an online platform where all the participants can log in easily and provide their feedback. This electronic platform will need to take into account their needs and requirements of patient and try to increase their engagement with the project objectives.

Involved User Groups

- Patients/Forum participants: Patient involvement is expected to reveal issues of usability and support the design of the online forum sot that it can be easily used by patients and increase their engagement with the project objectives
- Researchers/Consortium Members: Consortium members will also need to

participate to the online forum and set discussion topics based on the project needs. Therefore, the easy and intuitive use of the forum functionalities will help them to efficiently collect the feedback of patients

Evaluation

The possible methodologies that can be used under the current task include:

- Prototyping for the assessment of the issues of usability related to the structure of forum topics and the presentation of newly added comments
- Participatory design and Co-Discovery for the active involvement of users in the design process and the collection of new ideas and approaches for the effective sharing of their experiences regarding the management of asthma
- Story Boarding can help for to define the system interaction sequences and how the topics of discussions are presented

6.6 MyAirCoach Methodology for User Assisted Implementation

The third and final pillar of the User Centred Design approach of the MyAirCoach project is the creation of the plan for the assessment of user feedback during the actual implementation stages of the project. In this direction the MyAirCoach project is aiming to involve all the targeted user groups (asthma patients and their families, healthcare professionals and medical researchers) and in addition seek the help of experts outside the project consortium that can offer crucial insights for the implementation of system components and the design of Human Computer Interfaces.

- The support of the development activities of hardware components and the formation of the Wireless Body Area Network(WP3)
- The support of the definition of computational modelling components, the development of the intelligent information processing for the understanding of asthma, and the implementation of the overall decision support system (WP4)
- The development of the MyAirCoach Personal Guidance and Support application in addition to the formation of the Virtual Community Platform (WP5)
- The integration of the system components in a unified framework (WP5)

T3.1	**Definition and planning of the MyAirCoach sensor components**	**IHP**
T3.2	**Prototype development and assembly of the BAN**	**IHP**
T3.3	**Algorithm and embedded software development**	**IHP**

Methodology

The above couple of tasks is aiming to define and functional components of the inhaler sensor-based inhaler that is foreseen by the MyAirCoach project and to implement a compact device that can be connected in the Wireless Body Area Network of the asthma patient. In this direction, the involvement of actual patients and their doctors can lead to useful conclusion regarding the usability of the device and the avoidance of possible risks in the proper use of the inhaler.

Involved User Groups

- Patients: Patient involvement is expected to reveal issues of usability of the device and underline their concerns regarding the sensing capabilities of the prototype inhaler. Although the protection of privacy in the UCD framework has been addressed in the responsible task (T8.3 Ethical, safety and mHealth Barriers Manual) the current task will allow the understanding of the acceptability of the device in relation to privacy issues.
- Doctors: The involvement of doctors in the implementation processes of the above task can contribute to the identification of important safety concerns that should be addressed such as possible interference with the proper use of inhalers or issues of cleaning and sterilisation of the sensing device.

Evaluation

The possible methodologies that can be used under the current task include:

- Usability tests will help to identify any possible risks or interferences to the proper use of the inhaler
- Standards inspection will underline the characteristics of the device that may be in disagreement with medical device regulations
- Feature inspection will allow the definition of the list of features that adequately characterise the proper function of an inhaler with sensing capabilities, and allow to determine if the proposed design covers the mandatory components of the list.

T4.2	**Signal processing for asthma –related indicators**	**UPAT**
T4.4	**MyAirCoach clinical state prediction engine and risk assessment**	**UPAT**

Methodology

The current task will be responsible for the development of novel algorithmic approaches that will be used for the extraction of important indicators and risk factors regarding asthma condition. The outputs of all developed components will be used by patients and their doctors for the personalised understanding of asthma progression and will help them manage asthma more effectively. When viewed, from the perspective of medical researchers, the current task will be responsible for the creation of tools that can help them study and understand underlying mechanisms of asthma and support novel medication approaches.

It is therefore evident that the user perspective will play an important role in the development of these components and the production of tools that help all involved users to better understand the parameters that affect asthma condition, either in a personalised of general approach.

Involved User Groups

- Patients: Patient involvement will allow the understanding and determination of the most important measures to calculate and present for the easier understanding of their current condition and the proper use of medication.
- Doctors: The involvement of doctors will help to direct the development of algorithms in areas that hold the promise of increased clinical significance so as to allow practitioners to supervise the condition of their patients more efficiently.
- Researchers: The involvement of researchers will support the development of research tools that may be used for the identification of important unknown characteristics of asthma disease and lead to new approaches of medication

Evaluation

The possible methodologies that can be used under the current task include:

- Expert review can be used for the collection of feedback by researchers outside the MyAirCoach consortium that have better experience in the processing of medical information for the extraction of clinically important indicators.

- Heuristic evaluation can reveal issues of usability and easy understanding of the proposed user interfaces especially for the case of researchers where the user inputs and controls will be more complicated

T4.3	Multiscale computational modelling of airways and respiratory system	ICL

Methodology

The current task is aiming to develop detailed and personalised patient models covering the most important aspects of asthma disease. Therefore, the feedback of healthcare professionals and especially medical researchers will form the basis upon which the models of asthma patients will be designed and optimised for the optimal representation of the most important parameters that affect asthma disease

Involved User Groups

- Doctors: The involvement of doctors will help to separate and summarise the most important parameters affecting asthma disease, and will allow translating this experience in a representative and accurate patient modelling framework.
- Researchers: The feedback of medical researchers will help for the understanding of the relations between parameters that hold increases clinical significance and help to the generalised modelling of asthma disease in order to represent these correlations in an effective manner.

Evaluation

The possible methodologies that can be used under the current task include:

- Expert review will be the main method for the collection of contribution from healthcare professionals as described above.

T4.5	Personalised context-aware, medical information visualisation and Decision Support System	CERTH

Methodology

The current task will be responsible for the creation of a decision support system for both patients and their doctors that will present through intuitive and informative visualisations important parameters of patient medical history and allow doctors to supervise their patients and patients themselves to effectively manage their condition.

In this regard, the implementation of all the related components should be strongly linked to the needs and requirement of doctors and patients.

Involved User Groups

- Patients: The fundamental objective of the MyAirCoach project is to support and enhance the self-management capabilities of users through novel mobile health technologies. As such the feedback for the current task will allow the continuous connection of the opinions of patient with the implemented functionalities of

personalised decision support.

- Doctors: In a similar manner as above the involvement of doctors during the deployment of the current task will allow the adaptation of the offered functionalities and user interfaces for the optimum usability of the doctor oriented front-end of the system.

Evaluation

The possible methodologies that can be used under the current task include:

- Usability tests and performance measurements can be used for the understanding of the causes that lead users (patients and doctors) to mistakes or reduce the effectiveness of system use
- Think aloud protocol holds the promise to offer an insight to the cognitive processes of users during the use of the system and allow the developers to understand the causes of common mistakes and misconceptions and adapt the system accordingly
- Log-files analysis can be used for the anonymised collection of user actions within the system, that can reveal important issues of usability and utilisation of the available functionalities based on the large amounts of data that can be aggregated if a large number of patients and doctors uses the system for an adequate period of time.

T5.4	System integration	CERTH

Methodology

The current task will be responsible for the integration of all the MyAirCoach components in a unified and functional system. Even if the majority of usability and functionality related issues will be resolved within the respective tasks, the integration task can be possibly benefited from the collection of user feedback in regards to the combination of functionalities within a common framework.

Involved User Groups

- Patient and doctors can be involved for the conceptual separation of functionalities in the integrated system for their easier understanding and use
- Experts outside of the projects consortium can suggest alternative approaches for the integration of components and support the standardisation of the overall system.

Evaluation

The possible methodologies that can be used under the current task include:

- Usability tests and performance measurements can be used to evaluate the usability of the overall system and indicate areas that can be benefited from changes.
- Expert review from researchers and developers outside the project consortium can support the integration processes with new perspectives and alternative solutions
- Standards inspection can be used for the compliance of the overall system with commonly accepted development approaches and quality standards.

7 Overall MyAirCoach Methodology for User Centred Design

The following diagram (Figure 40) summarises the positioning of user centred design in the timeline of project. As it is indicated in this diagram the current deliverable will provide the basis for the design and evaluation of the MyAirCoach system based on the identification of user groups, the understanding of the most important user requirements and the definition of the specific goals and use cases that will be used in the evaluation stages. Furthermore, the definition of the UCD methodology will guarantee the connection of the project's outcomes with the actual needs of users through continuous evaluation feedback in the loop of design and development. Finally the diagram also shows the continuation of UCD and its transformation to market analysis and user needs analysis after the identification of any project component that is considered to have increased commercial value.

7.1 MyAirCoach Advisory Patient Forum

In the framework of the MyAirCoach project, the main tool for the collection of feedback by patients will be the Advisory Patient Forum as it was formed during the T6.1 or the project "Creation of the MyAirCoach Consultative Patient Forum" and described in D6.1. In order to allow the fast and efficient communication with the forum members an online private area was created in the project's website that will be managed by EFA and AUK and technically maintained by CERTH (see Figure 38). This online forum is offering the possibility to consortium members to introduce topics of interest and ask for the comments or suggestions of patients. Currently the online advisory patient forum has been used for the definition of instruction for MDI inhalers that are not only accurate but also easy to understand by patient. Indicative of the bidirectional benefits of this process is the comment of one of the forum participants where she mentions how the process of creating a new instructions manual for MDI helped her use her medication more effectively ()

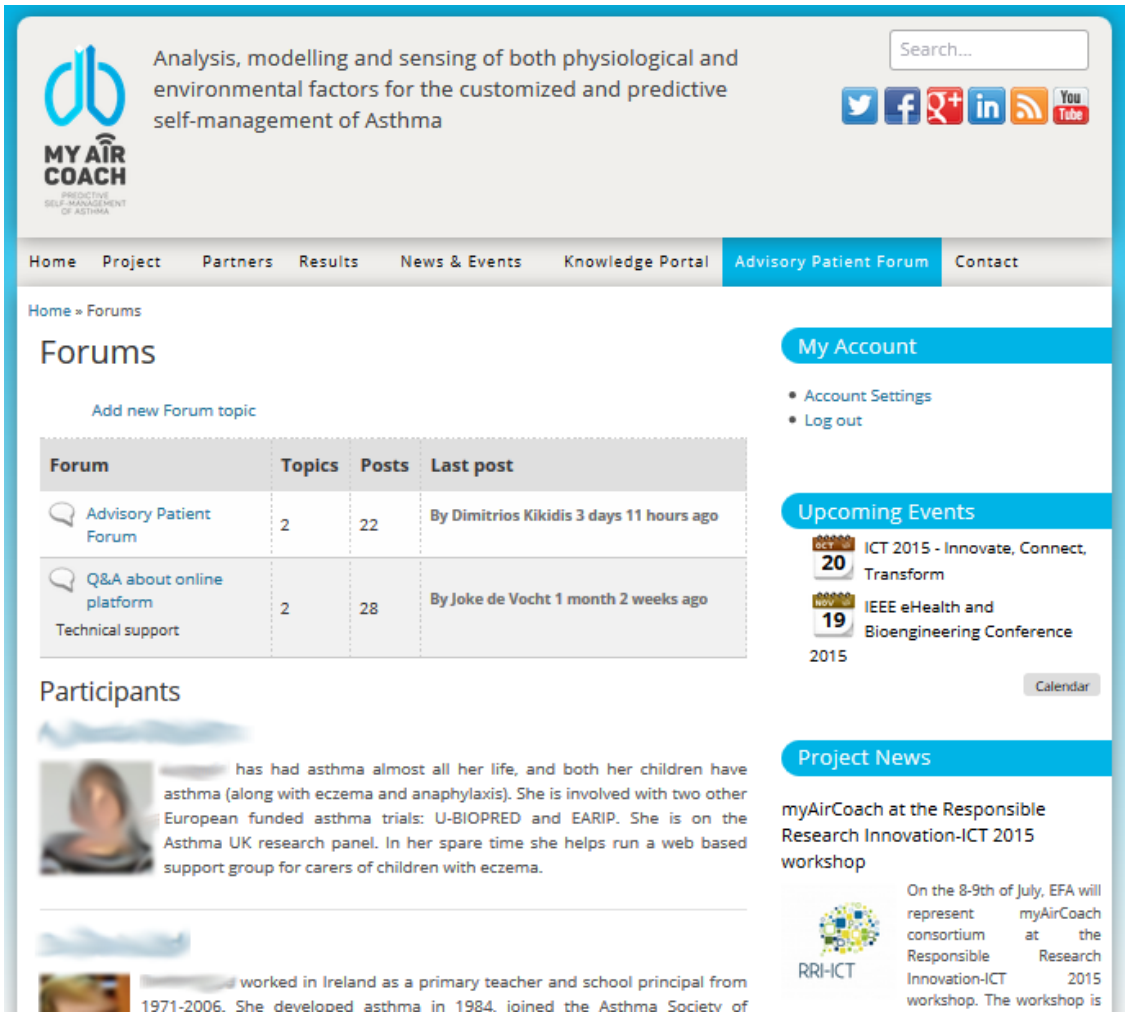


Figure 38: Online private platform of the MyAirCoach Advisory Patient Forum

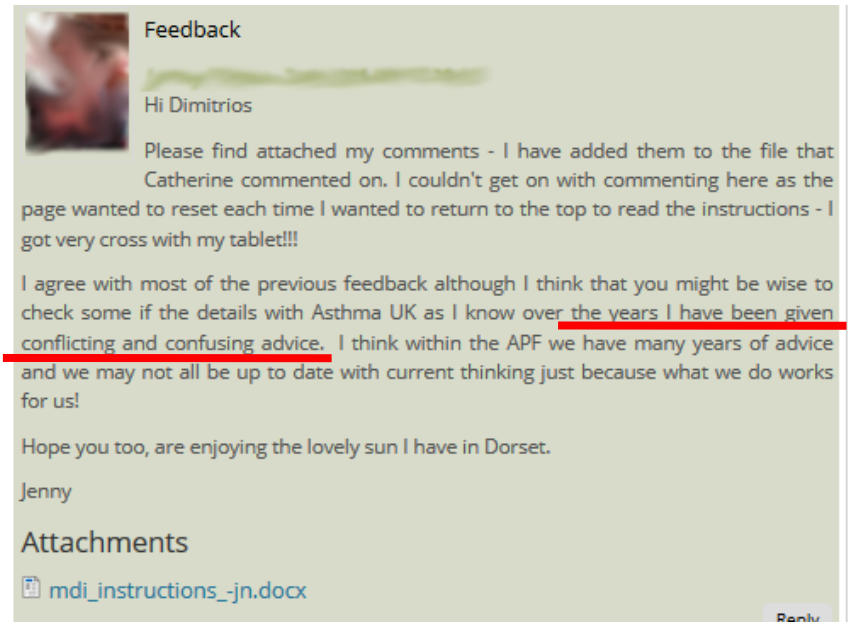


Figure 39: Indicative response during the APF discussions regarding MDI instructions

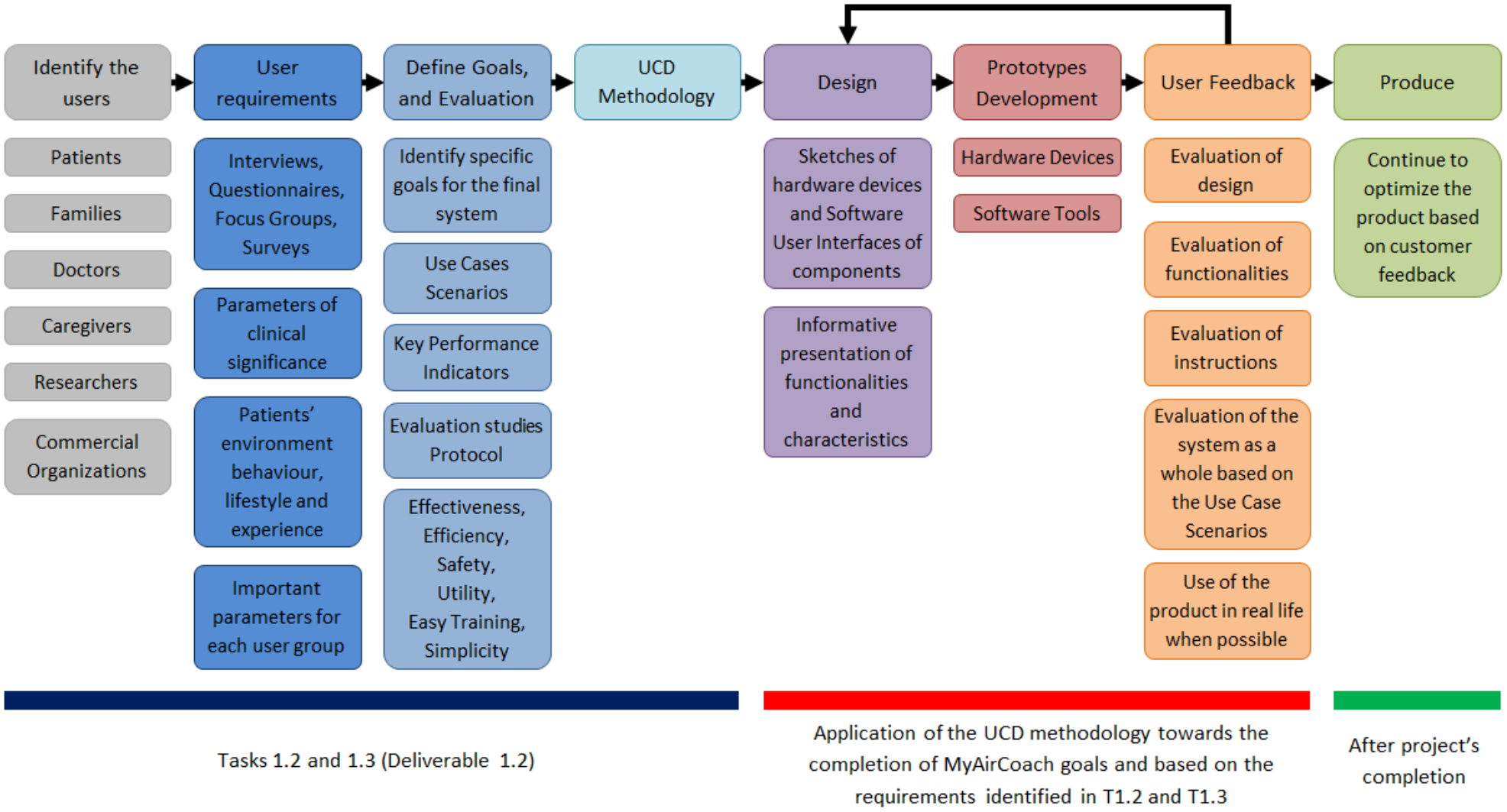


Figure 40: User-Centred Approach of MyAirCoach[49]

8 UCD Product Life-Cycle Approach

Parallel to the work of the MyAirCoach and within its activities, the projects consortium should also focus on the dissemination and exploitation activities of the final system. Figure 41 displays the product life-cycle of MyAirCoach by adding an additional iteration as it relates to the launching and exploitation stage of the final system. Market research focusing on all the related user groups will allow the extraction of usability issues and additional requirements that future designs and developments of MyAirCoach could address. Users' satisfaction with the devices and software tools of MyAirCoach will be evaluated in real life, allowing the further improvement of the system in newer versions and after the completion of the MyAirCoach timeline.

Furthermore, and in the case of a subsystem or specific component of MyAirCoach is finalised before the completion of integrated system, and based on the assumption that it can be launched and exploited as an independent component, the same approach can be used for the improvement of subsequent versions.

More specifically tasks T7.2 "Exploitation and MyAirCoach business models" and T7.3 "IPR management" will be responsible for this process and the definition of exploitation plans based on the specific outcome of the project that is considered to have increased commercial value.

8.1 Market Research and User Experience Research

Requirements and enhanced functionalities of the myAirCoach integrated system and individual tools and components may be identified through proper marketing research and user experience research.

This phase may find requirements and new findings that lead to further iterations of myAirCoach and thus completes the product life-cycle approach depicted in Figure 41. The further step added to the myAirCoach UCD development process includes the evaluation of the final product through

- Summative usability evaluations
- User experience evaluations
- Marketing research

The user experience of the myAirCoach system goes beyond usability and additional user experience parameters like design factors. User expectations for instance can be evaluated to collect information about the potential usage of the integrated system and in order to generate new requirements for future iterations and releases of the tools. Marketing research can allow obtaining such requirements not covered through usability and user experience evaluations and is crucial for an iterative enhancement and towards the commercial exploitation of the myAirCoach system.

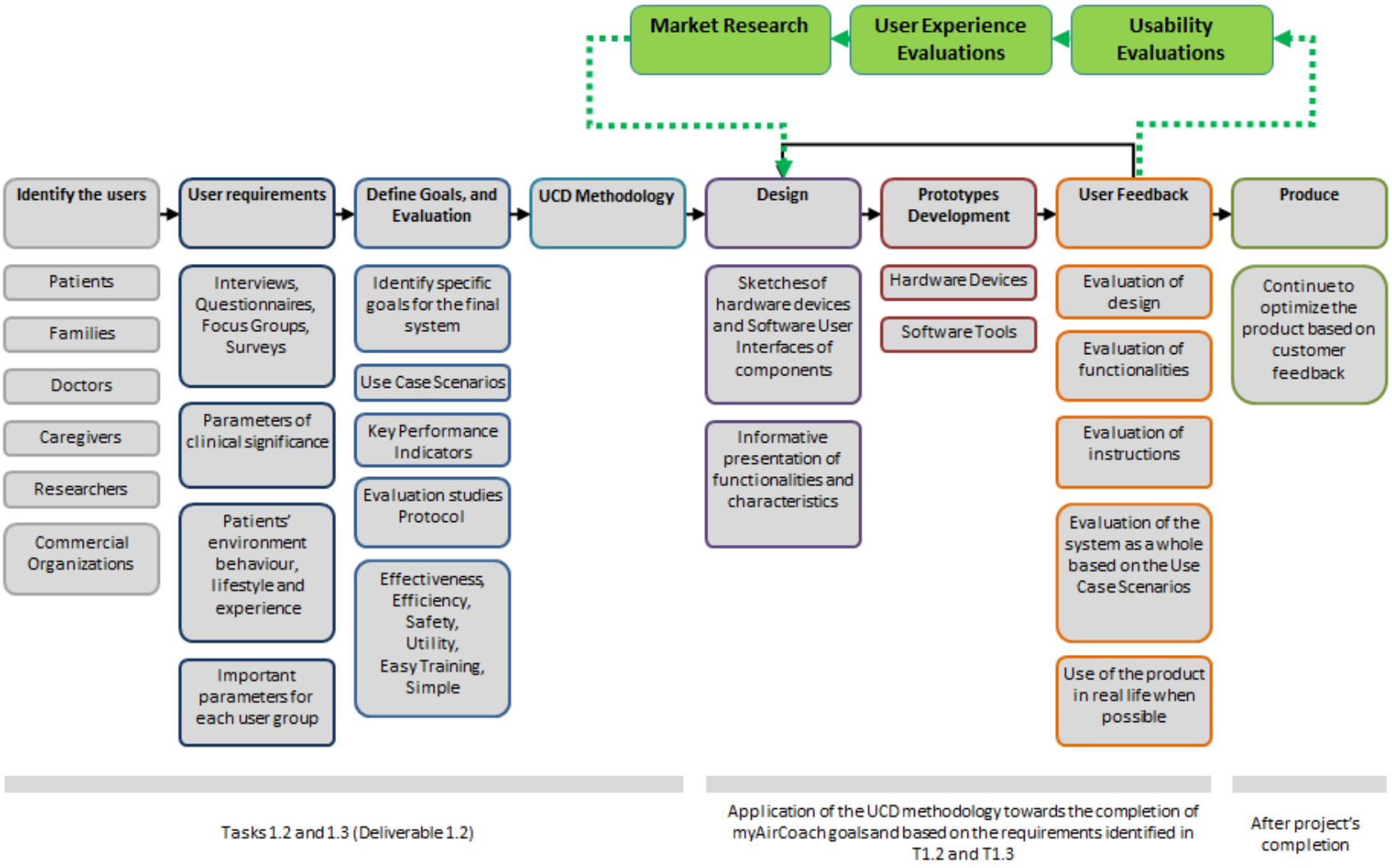


Figure 41: MyAirCoach User Centred Design Approach enhanced with stages for Product Lifestyle Evaluation

9 Conclusions

The current document aims to constitute the blueprint for the design and development of the MyAirCoach system on the basis of the needs and requirements of the intended user groups. More specifically the first sections position the MyAirCoach project in the healthcare environment and outline the importance of user involvement towards the realisation of the project objectives. A methodology of focus groups followed by surveys with the two primary user groups (people with asthma, and asthma healthcare professionals) was used and the opinions of 249 people with asthma and healthcare professionals from across Europe were captured. Analysis of the results led to the identification of 12 priority needs which theoretically could be addressed by the MyAirCoach system. These were:

1. Better use of action plans by provision of an action plan on a mobile phone
2. Improvements in inhaler technique
3. Monitoring of medication usage and adherence
4. Alerting patients to when their individual triggers may be present
5. Improved understanding of an individual's asthma
6. Prediction or earlier identification of exacerbations, enabling earlier treatment
7. Sharing of anonymised data to aid research
8. Data collection for clinical trials
9. Better definition of asthma phenotypes
10. Increased interactions between HCPs
11. Enable remote feedback from HCPs to patients
12. Identification of side effects of medication

The project consortium then developed 24 use cases in response to these needs and subsequently evaluated and prioritised them. Eleven of the 24 were felt to be achievable within the timeline of this programme, and six were judged to be high priority. These were then translated into the following goals for the MyAirCoach system.

- Use environmental measurements for the protection/ information of the user
- Ongoing monitoring of asthma to provide objective evidence of a person's condition to their healthcare team
- Use the myAirCoach system to monitor asthma control and enable early detection of the exacerbations
- Use the myAirCoach system to provide an electronic version of a patient's asthma action plan
- Use the myAirCoach system to monitor how regularly patients are taking (or not) their medication
- Use the myAirCoach system to create and/ or modify the action plan of a patient

The finally selected set of use cases will not only be a guide for the development of the system but will also form the basis for the evaluation processes during the tasks of WP6 “MyAirCoach Evaluation”.

The next chapters of the deliverable focussed on the planning of User Centred Design processes within the MyAirCoach, through the identification of important system components that can be optimised based on the users’ feedback. More specifically the most common and widely used methods of user assessment were summarised providing a reference manual to be used by the consortium. Following this, the majority of project tasks were analysed from the users’ point of view, and possible methodologies for the solution of specific issues were identified.

It should be underlined that the UCD sections are not intended to form a strict plan but rather a basis for the deployment of UCD processes based on the developing needs of the project and should be used where appropriate within the project’s time schedule. The formation of the Advisory Patient Forum (D7.1 Assembly of the consultative patient forum) and the creation of the online platform will support the UCD deployment of the project and the involvement of patients whenever necessary. Finally, the document provided a short introduction to the connection of UCD with the exploitation activities of the project which will be described within WP7 “Dissemination and Exploitation”.

Finally it should be noted that there was great enthusiasm from both people with asthma and healthcare professionals for building the evidence base for mHealth and its potential to improve asthma management. It was very clear that different people will benefit in different ways and as such the myAirCoach system developed must have the ability to be both flexible and customisable to the individual. Given the complexities around self-management of a long term and highly variable condition like asthma, users are likely to engage only with the aspects of the system which are most relevant to, and which they themselves believe will most benefit them. The challenge in developing a system which can benefit all people with asthma is therefore to create a system with wide ranging functionality which is equally effective independent of which and how many of its functions are used by the individual. In this direction the current deliverable has set the basis so that the design and development processes of the MyAirCoach project are directly connected with the needs and requirement of users.

Appendix 1: Ethics application and approval documents

Health Research Authority
NRES Committee East Midlands - Derby
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS
Telephone: 01158839390

17 August 2015

Dr Stephen Fowler
Lecturer and Honorary Consultant in Respiratory Medicine
The University of Manchester
Education and Research Centre
Wythenshawe Hospital
Southmoor Road
M23 9LT

Dear Dr Fowler

Study title:	**mHealth to assist with the self-management of asthma: the opinions of individuals with asthma and of healthcare professionals on current and potential functions**
REC reference:	**15/EM/0360**
IRAS project ID:	**183623**

Thank you for your letter of 13th August 2015, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Assistant, Tad Jones, NRESCommittee.EastMidlands-Derby@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

Appendix 2: Topic Guide for patient focus groups

User requirements from people with asthma via focus groups

Aim of focus group:

1. To gain a better understanding of how acceptable people with asthma find the concept of using mobile technology to help them manage their asthma
2. To gain a better understanding of how feasible some of the proposed aspects of myAirCoach will be

Methods:

Number of participants: maximum of 8 per focus group.

Briefing: Patients will be informed with regards to the purpose of the focus group at enrolment.

Participant demographics: Participants will complete the asthma control test (ACT) questionnaire and demographic data will be collected anonymously prior to start of the focus groups (questions below).

Questioning strategy: A funnel method of questioning (broad to specific) will be used. This type of questioning makes it possible to hear the participants' general perspectives in the early part of each discussion, as well as their responses to the researchers' specific interests later in the discussion. Follow-up questions and prompts will be used to probe for further details if necessary.

Duration: 2 hr

Location:

- one focus group will be held with patients in Manchester, UK
- one focus group will be held with patients in London, UK
- one focus group will be held with patients in Leiden, Netherlands

Recruitment:

- UK: via Asthma UK's Research and Policy volunteers and supporters on social media; University of Manchester and Imperial College London contacts
- Netherlands: via EFA's network of patient organisation contacts, especially Longfonds (Dutch respiratory organisation) and Leiden University Medical Centre contacts

Demographic data to be collected via anonymous written questionnaire:

1. Age:
2. Gender:
3. Occupation:
4. Relationship with asthma:
    a. Individual with asthma

   b. Parent of a child with asthma
   c. Carer of someone with asthma
5. Asthma severity [check box]
   a. mild
   b. moderate
   c. severe
6. Number of asthma attacks in the previous year (an asthma attack is a period when you experience new or increased asthma symptoms (including wheeze, cough, breathlessness or waking up at night due to these symptoms) that lead to treatment with oral steroids for at least 3 consecutive days or to hospitalisation.
7. Current prescribed asthma medication(s)
8. Owner of mobile phone & type of mobile phone
9. Ethnicity

A. White

☐

B. Mixed

☐ Black Caribbean and White

☐ Black African and White

☐ Asian and White

☐ Any other mixed background (please specify: _____)

C. Asian

☐ Indian

☐ Pakistani

☐ Bangladeshi

☐ Any other Asian background (please specify: _____)

D. Black

☐ Black Caribbean

☐ Black African

☐ Any other Black background (please specify: _____)

E. Chinese

☐ Chinese

☐ Any other Chinese background (please specify: _____)

F. Any other ethnic background

☐ Please specify: _____

10. Home location:
    a. Country
    b. City

    First part of postcode (e.g. E1, SW9, BT38 etc) _____

Theme/prompts	**Questions**
Current use of mobile health technology – *mobile health technology can be used to help monitor the health of patients with asthma.*	
Knowledge and use of technology for asthma management / current asthma apps	1. We would first like to ask what you know about mobile technology and asthma, and whether you have any experiences or expectations of using it? ***[Follow up questions:*** *Can you tell me about your experiences of using it? Was it useful or not? Why did you decide not to try it? How long did you use it for? Why did you stop using it?]* 2. What would encourage you to use or discourage you from using mobile health technology to manage your asthma? ***[Prompts:*** *User friendly app, sise of additional hardware]*
Mobile health technology concept - *the concept of mobile health technology is to collect physiological, environmental and behavioural data that can be used to provide feedback that may help patients control their asthma. We would like to discuss what parameters you think would be useful to monitor. These parameters may include data that is collected using additional external devices – i.e., devices that are not built into a mobile phone, such as home monitoring devices and sensors.*	
Proposed measurements	3. What measurements do you think might help you control your asthma or prevent asthma attacks? ***[Prompts:*** *physiological factors such as measurements of lung function, behavioural factors like medication usage,*

	are there environmental factors that could influence your asthma control that could be measured?] ***[Follow-up questions:*** *Why do you think that would be useful? Are you aware of any devices that measure that?]* ** Items not mentioned in this original discussion - that are of specific interest to the research team - should be mentioned by the facilitator in following question* 4. There are some additional parameters that haven't been mentioned that could be measured and we would be interested in hearing your opinion of them, they include: **Environmental factors, such as;** ▪ your location ▪ the pollution, temperature and humidity levels in your environment **Physiological factors, such as;** ▪ lung function measurements such as spirometry, and levels of exhaled nitric oxide ▪ passive breathing related measurements such as breathing rate, cough counting, breath sounds and exhaled breath temperature ▪ Heart rate **Behavioural factors, such as;** ▪ your levels of activity, e.g. whether you're running, walking or sitting still ▪ medication use and inhaler technique **[Follow-up questions:** Do you think that would be a useful measure? Could you see yourself using it? Are you aware of any similar devices?]
Burden of inputting data (sensors / measures)	*To help get accurate information and detect changes in your asthma control some of the aforementioned measures would be required on a regular basis. Some of the measures could be taken 'automatically' – for example, location, heart rate and environmental conditions. This means that patients wouldn't have to do anything to allow the measure to be taken. Other measures will require some interaction on the part of the patient – for example completing measures of lung function and inputting the*

	results. *We would like to understand how often you would be willing to take these measurements* 5. What are your opinions about taking regular measurements and how long would you be willing to spend completing and inputting the measurements? **[Prompts:** three times per day, once per day, three times per week, once per week, once per month] **[Follow up questions:** what level of control would you like to have over the schedule / timing of measurements and would this affect your willingness to complete the measurement and input the data? Would you be willing to take the measurements if your data were recorded automatically?] 6. We would also like to understand how often and how long you would be willing to spend taking each specific measurement: • spirometry • exhaled nitric oxide • exhaled breath temperature **Automatic data collection** *Some measurements can be collected automatically, which would prevent the need for patient involvement. This 'automatic data collection' would usually require the patient to wear and/or carry a device. We would like to know your opinions on this.* 7. In general, what are you opinions on having your data recorded automatically and carrying additional devices? 8. Specifically, what are you thoughts on: • your inhaler usage and technique being recorded automatically by an inhaler or a device on your inhaler?

	Follow up questions: would you be willing to swap the type of inhaler you use to facilitate these measurements? • the recording of your heart rate and activity levels by wearing a wristband? **[Follow up questions:** *would you wear this device day and night? What would influence whether or not your wore it?]* • your location being measured by your mobile phone to determine location of inhaler usage? • environmental conditions being measured by GPS and/or a wearable device? **[Follow up questions:** *what would you consider an acceptable size of a sensor? Would you be happy carrying/wearing a sensor?]* • your breathing rate and sounds being measured by a stick on 'Smart plaster' that contains a small microphone? **[Follow up questions:** *What would you consider an acceptable size of a wearable sensor? Would you consider wearing a sensor on your chest?]*
Burden of inputting data (questionnaires)	*Questionnaires offer an insight into how you are feeling. The questions refer to your asthma, your symptoms and how you're feeling overall. We'd like to understand whether you would be willing and, if so, how often you would be willing to give questionnaire feedback via an app.* 9. Would you be comfortable providing feedback on your asthma symptoms and how you're feeling via an app? 10. What factors do you think need to be considered when designing questionnaires? **[Prompts:** length of question, methods of response - narrative vs tick box response, number of pages, number of questions, navigation between pages]

	11. What are your preferences in terms of the timing of questionnaires? **[Prompts:** would you prefer to respond in the moment – i.e respond to a prompt there and then or at the end of day – i.e. like a diary to reflect on the day?]
Alerts and reminders	*Mobile health technology allows alerts and reminders to be sent directly to your mobile phone.* 12. What alerts and reminders do you think would be useful for the management of your asthma? **[Follow up questions:** why might that be useful? Do you often forget to do that?] ***[Prompts:** think about physiological, behavioural and environmental factors]* ** Items not mentioned in this original discussion - that are of specific interest to the research team - should be mentioned for discussion by the facilitator in following question* 13. There are additional alerts and reminders that could sent, and we would be interested in hearing your opinion of them, they include: **Environmental factors:** ▪ Would you like to be alerted when you enter an environment with high levels of pollution, adverse temperatures and humidity levels that may affect your asthma? **Physiological factors:** ▪ Would you like to be alerted when your lung function measurements have improved or deteriorated? **Behavioural factors:** ▪ Would you like reminders to take your medication, lung function measurements and to complete questionnaires? ▪ Would you like notification of poor inhaler technique?

	▪ Would you like reminders for appointments? ▪ Would you like notification of your activity levels? 14. How important would the following aspects of an alert and reminders system be? ▪ Being able to customise alerts and reminders ▪ Being able to set goals ▪ Motivational messaging ▪ Problem solving ▪ Being able to control the timing of alerts and reminders ▪ Language and tone of the alerts and reminders ▪ Feedback (about how your asthma is doing based on all the information collected and any changes you could make) ▪ Are there any additional aspects that aren't covered here?
Clinical & peer support	*Via alerts and reminders mobile health technology systems can help you manage your asthma – this may include advice on when to take your inhaler, or changes to your routine or environment – for example if there were levels of high pollution.* *We would like to understand what other support, in addition to the alerts and reminders, you think may be useful would.* 15. What support would you like to have available to help you understand the information provided by mobile health systems to better manage your asthma? **[Prompts:** access to GP, specialist asthma nurse, speak to other users, intuitive interfaces with information about asthma, FAQs] 16. How would you like to access this support? **[Prompts:** via telephone call, via app, via email, via text message, via website, via online support forum] ***[Follow-up questions:*** *Why would you prefer that method?]*

	17. If support were available via an online forum, what type of support would you like it to offer? **[Prompts:** opportunity to chat to other mobile technology users, share tips, speak to an asthma nurse or doctor, provide written information and guidance (action plans, understanding your asthma etc)]
Accessing personal data / analysis	*Mobile health technology systems can track and analyse key information about your asthma – using the sensors and measurements we talked about earlier. After the information is collected, the systems will analyse it and provide advice to help you manage your asthma. We would like to understand whether you would like to see the data analysis and how you would like to access the information.* 18. Would you like to have access to the data analysis, based on the measurements and feedback you provide to the system? [*This could be in different formats but would allow you to see how each of the measures link up and give you a personal profile of your asthma*] 19. What factors would influence or change the way you access your personal data? **[Prompts:** symptom severity, whether your data are reviewed by a doctor, nurse, number and content of the myAirCoach alerts, time of year, how interesting or engaging the content is, incentives]
Adherence to system recommendations	*Mobile technology systems can provide you with feedback and recommendations based on the analysis of various measurements. This feedback may include the suggestion to step-up or step-down your medication or to visit your GP.* 20. Would you be willing to adhere to the recommendations from mobile technology? **[Follow-up questions:** Would you just accept the

	recommendations? What would give you confidence in the recommendations?] **[Prompts:** would it help to; see the data, see an explanation of why the suggestion was made (links to see a treatment guidelines), discuss the recommendations either in person, over the phone or online to a Dr or healthcare specialist, knowing the data has been reviewed and the recommendation approved by a Dr, knowing the system has been approved by your Dr]
Privacy	*Mobile technology systems collect personal and sensitive information. We'd like to understand how you feel about the sensitivity and privacy of the data it collects and how this data will be shared with others.* 21. What are your thoughts about using mobile technology with respect to privacy? 22. Are there any particular sensors or measurements that you question more than others in relation to privacy? **[Prompts:** location data, sound sensors, physiological data] 23. What information would you like to have to help you understand how your data will be stored, analysed and shared? **[Prompts:** overview of privacy safeguards, overview of who can access your data, security elements built in, use cases / scenarios to demonstrate how it will be used in practice] 24. What process or permissions would you like to go through in order to share data access? **[Prompts:** one time permission for each user, permission approved for all healthcare professionals etc] 25. How do you feel about your data being shared with the following groups: ▪ GP / asthma nurse / consultant ▪ Clinic staff (non-medical) – e.g. receptionist ▪ Emergency healthcare (ambulance, A&E department)

	▪ Researchers
Goal setting	*Goal setting is a feature often used by mobile health technology. We'd like to understand whether the setting of personalised goals would increase your motivation to use or keep using mobile technology.* 26. Is it important to have the ability to set, manage and monitor progress against your goals? 27. What areas would this help with? **Prompts:** medication adherence, checking whether you're getting benefit from the system, reminders to get new prescriptions.
Design and branding of devices	*Mobile technology systems come in various shapes and sizes. We would like to understand your views on how these devices should look and feel and what factors should be taken into account when designing them.* 28. What design factors would influence whether or not you use the device? **[Prompts:** size, number of different devices, doesn't interfere with the look and feel of my phone, being able to customise it] 29. How important is it to be able to customise the device (mobile app & hardware)? 30. How would you like to customise the device (mobile app & hardware)? **[Prompts:** (for app) manual configuration of settings vs automated learning – e.g. it knows that you don't use a certain feature, or we already know your height so we won't ask you again etc., (for hardware) mounting type (ribbon, clip), colour, battery life, size]
Additional functions	31. Are there any additional functions or features that you would like to see incorporated into mobile technology?

Appendix 3: Topic Guide for HCP focus groups

User requirements from healthcare professionals via focus groups

Aim of focus group:

1. To gain a better understanding of how acceptable healthcare professionals find the concept of using mobile technology to help their patients manage their asthma
2. To gain a better understanding of how feasible some of the proposed aspects of myAirCoach will be

Methods:

Number of participants: maximum 8.

Recruitment: via University of Manchester and Imperial College London contacts. Focus on recruiting healthcare professionals who support people with asthma in primary care, including nurses and community pharmacists.

Location: one focus group will be held with healthcare professionals in Manchester, UK.

Demographic data to be collected via anonymous written questionnaire:

11. Gender
12. Ethnicity
13. Profession: [check box]:
    a. General practicioner (GP)
    b. Practice Nurse
    c. Nurse with asthma diploma
    d. Community pharmacist
    e. Clinician
    f. Clinical psychologist
    g. If none of the above, please specify
14. Setting: [check box]
    a. primary care
    b. secondary care
    c. tertiary care
    d. specialist clinic
    e. community health
15. Asthma severity of your patients [check box]:
    a. mild
    b. moderate
    c. severe
    d. all levels of severity
16. Location of practice:
    a. City

b. First part of postcode (e.g. E1, SW9, BT38 etc)

Theme	Potential questions
Current use of mobile technology	
Current practice	1. Please describe a typical asthma patient appointment in your clinical setting. [Prompts: what happens, what technology do you use?] 2. What measurements do you take and how frequently do you take these? 3. How do you use these measurements/data, what clinical decision making do they inform?
Adherence and Goal setting	4. In your experience, is it important for patients to set, manage and monitor progress against goals? 5. What areas would this help with? [Prompts: medication adherence, informing whether they are getting benefit from the system, reminders to get new prescriptions] 6. Do you currently recommend/advise/support your patients to set goals about their asthma? [Probes: How do you do this?, How do you monitor progress?] 7. [Prompts: write them down as part of diary / peak flow monitoring, part of the asthma review]
Use of technology for asthma management / current asthma apps	8. Do you recommend any mobile technology or apps to your patients to help manage their asthma at the moment? a. If yes – what are the key things that you find useful about the asthma apps you recommend? b. If no – why do you not recommend any asthma apps at the moment? [Prompts: not aware they existed, cost, too time consuming, too invasive, no evidence (anecdotal or empirical) of effectiveness]

	9. What factors would influence whether or not you would recommend technology to help with managing asthma? 10. [Prompts: user friendly app, evidence of effectivesness, endorsement by a colleague, size of any additional hardware]
myAirCoach concept - *Provide an overview of myAirCoach concept as a system which senses your physical environment and key asthma markers in order to provide real-time feedback, advice and monitoring to improve asthma management.*	
Acceptability of sensors / measures	*myAirCoach would like to monitor some things which will help to indicate whether your patient's asthma is well controlled.* 11. What are your thoughts about the usefulness of the following measures?: ▪ blood pressure ▪ pulse ▪ levels of activity, e.g. whether you're running, walking, sitting still ▪ body temperature ▪ location ▪ hormone changes and menstrual cycle (if relevant) ▪ breathing rate / respiratory cycle ▪ coughing ▪ breath sounds ▪ medication use – e.g. if /when they take their inhaler ▪ inhaler technique ▪ wheezing ▪ lung function tests –e.g. peak flow ▪ FeNo in exhaled breath (other biomarkers?) ▪ pollution levels in the patients' environment ▪ ambient temperature in the patients' environment ▪ humidity in the patients' environment 12. What are the pro's and con's about any of the above sensors / measures? 13. Are there any additional measures that haven't been mentioned above that you would find useful?
Alerts and reminders	*From time to time the myAirCoach system will send your patients alerts and reminders. This might be a reminder to take their inhaler or to take part in one of the active measures. It*

	might also be to alert them to something that might impact their asthma – for example if there are high pollution levels and this is a known trigger for their asthma. 14. Do you think there is value in sending alerts, reminders and/or advice to patients? a. If no- Why do you not? b. If yes- Would you like to be able to send alerts and/or reminders? 15. If yes, how would you like to send the alerts and/or reminders [Prompts: via text message, via an app alert, via email, phone call] 16. What factors do we need to consider when designing the alerts and reminders? [Prompts: easy to use, intuitive interfaces, ability of the patient to respond, ability for health professional to check the patient's condition after a message, language, tone] 17. Based on your experience, do you think any of the following aspects of the proposed alerts and reminders system would improve asthma management? ▪ Goal setting ▪ Motivational messaging ▪ Timing of messaging ▪ Problem solving ▪ Feedback (about how their asthma is doing based on all the information collected and any changes they could make) ▪ Are there any aspects that aren't covered here?
Clinical & peer support	*Via alerts and reminders the myAirCoach system will help your patients to take steps to better manage their asthma – this may include advice on when to take their inhaler, or changes to their routine or environment – for example if there were levels of high pollution.* *We would like to understand what other support, in addition to the alerts and reminders, you would like to be available.* 18. What support would you like to be available to help your patients understand the information which myAirCoach tells

	them to better manage their asthma? [Prompts: access to GP, specialist asthma nurse, speak to other users, intuitive interfaces with information about asthma, FAQs] 19. Would you prefer this support to be provided by a central facility of HCPs or by the patient's individual HCPs (ie yourselves) 20. If relevant, how would you like to provide this support? [Prompts: via telephone call, via app, via email, via text message, via website, via online support forum] 21. If support were available via an online forum, what type of information, support and functions would you like it to offer? [Prompts: opportunity to chat to other myAirCoach users, share tips, speak to an asthma nurse or doctor, provide written information and guidance (action plans, understanding your asthma etc)]
Accessing personal data / analysis	*The myAirCoach system will track and analyse key information about your patients' asthma – using the sensors and measurements we talked about earlier. After the information is collected, the system will analyse it and provide advice to help your patients better manage their asthma. We would like to understand whether you would like to see the data analysis and how you would like to access the information.* 22. How and how often would you like to access the measurements and feedback data provided by your patients? [Prompts: via an app on your phone, log on to a secure website, emailed to you, what format should it be in e.g. data summary, pictures, pie charts,] 23. What format would you like to access the data in? [Prompts: data summary, pie charts, graphs, narrative, pictures or symbols] 24. How would you prefer to group or interrogate the data? [Prompts: by asthma severity, according to risk or number of adverse events] 25. Would you like to be alerted in case of a higher risk to your

	patients, for example in order to be able to contact them directly to provide advice and support?
Privacy	*We're conscious that some aspects of the myAirCoach system will collect personal and sensitive information. We'd like to understand how you feel about the sensitivity and privacy of the data it collects and how this data will be shared with others.* 26. As a professional, do you have any concerns about the use of such a system by your patients for privacy reasons? 27. What information would you like to have to help you understand how data will be stored, analysed and shared? [Prompts: overview of privacy safeguards, overview of who can access data, security elements built in, use cases / scenarios to demonstrate how it will be used in practice] 28. What safeguards would you like to have in place to ensure your patients' data is stored securely? [Prompts: password protection, data encryption] 29. If we used password protection, when and how often would you want this to be activated? [Prompts: each time you use the app, each time you complete a survey / enter information, only once when you first download it] 30. What process or permissions would you like to go through in order to share data access? [Prompts: one time permission for each user, permission approved for all healthcare professionals etc] 31. What safeguards or protections would you like to see in place for people accessing your patients' data on the other side [Prompts: pre-agreed access for health professionals, password protected login, clear protocol of how they are allowed to use that data] 32. Are there any particular sensors or measurements that would concern you more than others in relation to privacy? [Prompts: location data allowing tracking of other behaviour, e.g. linked to illegal activity, drug use, sound

	sensors]
Additional functions	33. Are there any additional functions or features that you would like to see incorporated into myAirCoach that we haven't already mentioned? 34. Overall, what would a new system have to have/do/demonstrate in order for you to adopt it into your practice?

Appendix 4: Patient Survey

Self-management programmes are beneficial for people to effectively manage their asthma. Despite these beneficial effects, self-management programmes are rarely used. Mobile devices that assist with the management of medical conditions are becoming widely available. This form of mobile technology is termed mobile health or mHealth.

We are a multidisciplinary team that is developing a new mHealth system designed specifically to help people with the self-management of their asthma. The first stage of this is to find out the opinions of people about the use of mHealth. We aim to use these opinions to create a 'user centred' mHealth system that will better enable people to manage their asthma.

The survey is comprised of 35 questions and should take approximately 15-20 minutes to complete.

By completing this survey, you agree for your responses to be used for research purposes. It will not be used in a manner that will allow identification of your individual responses. Anonymised data will be archived in an open data depository in order to make them available to other researchers in line with current data sharing practices.

Many thanks

myAirCoach team

1. In order to determine whether the opinions generated here can be generalised to a wider population, it is important that we collect some information about you and your asthma control.

Gender

- ◯ Male
- ◯ Female

2. Age (years)

3. Ethnic origin. Please use codes as listed

- ◯ White British
- ◯ White Irish
- ◯ Other White
- ◯ Mixed: White and Black Caribbean
- ◯ Mixed: White and Black African
- ◯ Mixed: White and Asian
- ◯ Other mixed background
- ◯ Indian
- ◯ Pakistani
- ◯ Bangladeshi
- ◯ Other Asian background
- ◯ Caribbean
- ◯ African
- ◯ Other Black background
- ◯ Chinese
- ◯ Other ethnic group

4. Occupation

5. First part of postcode (eg E1, SW9, BT38 etc)

6. On average during the past week, how often were you woken by your asthma during the night?

- ◯ Never
- ◯ Hardly ever
- ◯ A few times
- ◯ Several times
- ◯ Many times
- ◯ A great many times
- ◯ Unable to sleep because of asthma

7. On average during the past week, how bad were your asthma symptoms when you woke up in the morning?

- ◯ No symptoms
- ◯ Very mild symptoms
- ◯ Mild symptoms
- ◯ Moderate symptoms
- ◯ Quite severe symptoms
- ◯ Severe symptoms
- ◯ Very severe symptoms

8. In general during the past week, how limited were you in your activities because of your asthma?

- ◯ Not limited at all
- ◯ Very slightly limited
- ◯ Slightly limited
- ◯ Moderately limited
- ◯ Very limited
- ◯ Extremely limited
- ◯ Totally limited

9. In general during the past week, how much shortness of breath did you experience because of your asthma?

- ◯ None
- ◯ A very little
- ◯ A little
- ◯ A moderate amount
- ◯ Quite a lot
- ◯ A great deal
- ◯ A very great deal

10. In general during the past week, how much of the time did you wheeze?

- ◯ Never
- ◯ Hardly any of the time
- ◯ A little of the time
- ◯ A moderate amount of the time
- ◯ A lot of the time
- ◯ Most of the time
- ◯ All of the time

11. On average during the past week, how many puffs/ inhalations of short-acting bronchodilator (eg Ventolin/ Bricanyl) have you used each day?

- ◯ None
- ◯ 1-2 puffs/ inhalations most days
- ◯ 3-4 puffs/ inhalations most days
- ◯ 5-8 puffs/ inhalations most days
- ◯ 9-12 puffs/ inhalations most days
- ◯ 13-16 puffs/ inhalations most days
- ◯ more than 16 puffs/ inhalations most days

12. Have you had a severe asthma attack in the last year? Severe asthma attacks are defined by the occurrence of the following: Use of systemic corticosteroids (tablets, suspension or injection) or an increase from a stable maintenance dose, for at least 3 days or a hospitalisation or A&E visit because of asthma which required systemic corticosteroids.

- ◯ Yes
- ◯ No

13. If yes, number of severe asthma attacks

14. Current prescribed asthma medication(s) and dosage if known

Drug name

Drug name

Drug name

Drug name

15. What would you like from a mHealth system with regards to your asthma management?

Please tick all that apply

- [ ] A device/ system that could replace routine (eg annual) check-ups
- [ ] A device/ system that advises you when to seek medical attention
- [ ] A device/ system to help monitor your asthma yourself
- [ ] A device/ system that detects a deterioration in your asthma before you would notice it
- [ ] A device/ system to collect data that you can show your doctor, to demonstrate how your asthma has been
- [ ] A device/ system to use as part of your asthma action plan (provide you with instructions on how to better manage your asthma)
- [ ] A device/ system to offer education materials about your asthma
- [ ] A device/ system that tells you how to manage your asthma in an emergency
- [ ] A device/ system that can take measurements and update your medical records
- [ ] A device/ system that can tell if changes to asthma medication have improved your asthma
- [ ] A device/ system that can be used to call for emergency help during an asthma attack
- [ ] A device/ system to record treatment side-effects

Other (please specify)

16. mHealth systems allow for a variety of information to be collected that may help with asthma management. Which of the following information do you think would help you achieve better control of your asthma?

Please tick all that apply

- [ ] information about your environment (eg pollution, allergens (pollen), temperature and humidity in your area)
- [ ] Information regarding your lung function (eg peak flow and measurements of airway inflammation)
- [ ] Information regarding your breathing (eg your breathing rate and details of how often you cough)
- [ ] Information regarding your heart rate and activity levels
- [ ] Information regarding your stress levels
- [ ] Information regarding how often you're using your asthma medication
- [ ] Information regarding your inhaler technique (ie whether you are using your inhaler correctly)
- [ ] Information regarding your diet
- [ ] Information regarding the quality of your sleep
- [ ] information regarding your self-reported symptoms

Other (please specify)

17. Some mHealth systems could take measurements 'automatically'. This means that patients wouldn't have to do anything to allow the measurement to be taken. For these measurements to be collected you may need to wear or carry an additional device.

We would like to know what devices you would find acceptable to carry and use.

Please tick all that apply

- [ ] I would be happy for my inhaler technique to be monitored by a device built into or attached to my inhaler
- [ ] I would be happy for a device built into or attached to my inhaler to monitor my inhaler usage
- [ ] I would be happy for my heart rate and activity levels to be monitored via a wrist band
- [ ] I would be happy for the location of where I used my inhaler to be determined by GPS in my mobile phone
- [ ] I would be happy for my breathing to be monitored by a sensor that clips onto my clothing (belt or bra)
- [ ] I would be happy for my breathing to be monitored by a sensor that sticks directly to my chest (like a small plaster)
- [ ] I would be happy to make lung function measurements on a device that is kept at home

Other (please specify)

18. We would like to determine what physical features would affect your decision on whether a device/ system was acceptable.

How many additional devices (in addition to your inhaler) would you consider carrying/ wearing?

Please tick one option

- ◯ I wouldn't carry any additional devices
- ◯ I would carry/ wear 1 additional device
- ◯ I would carry/ wear 2 additional devices
- ◯ I would carry/ wear 3+ additional devices

Other (please specify)

19. mHealth systems may include an additional piece of home-monitoring equipment (no bigger than the size of a shoebox) that would be used at home

- ◯ I would be willing to have an additional home-monitoring device in my home
- ◯ I would NOT be willing to have an additional home-monitoring device in my home
- ◯ I don't know

Other (please specify)

20. How often would you be willing to wear a wristband that monitors your heart rate and activity levels?

- ☐ I would not wear a wristband
- ☐ I would wear a wristband all day (24 hour)
- ☐ I would wear a wristband for part of the day (2-8 hours)
- ☐ I would wear a wristband only at night
- ☐ I don't know

Other (please specify)

21. How often would you be willing to wear a sensor that attached to your clothing (belt or bra) to detect your breathing rate?

- [ ] I would not wear a sensor that clips onto my clothing (ie belt or bra)
- [ ] I would wear a sensor that clips onto my clothing all day (24 hours)
- [ ] I would wear a sensor that clips onto my clothing for part of the day (2-8 hours)
- [ ] I would wear a sensor that clips into my clothing only at night
- [ ] I don't know

Other (please specify)

22. What factors would influence whether you would consider carrying an additional device

- ◯ If it was discrete/ if it didn't interfere with an outfit (ie it wasn't noticeable)
- ◯ If it could be modified (eg you could change the colour/ appearance of the device)
- ◯ If it could fit in your pocket/ bag
- ◯ If it could be attached to a device already carried (eg a phone or inhaler)
- ◯ None of the above

Other (please specify)

23. Would you be willing to change your inhaler in order to have access to the mHealth system?

- [ ] I would be happy to change the brand of my inhaler (drug manufacturer)
- [ ] I would NOT be happy to change the brand of my inhaler (drug manufacturer)
- [ ] I would be happy to change the type of inhaler (ie change from a powder inhaler to a pressurised gas or vice versa)
- [ ] I would NOT be happy to change the type of inhaler
- [ ] I don't know

Other (please specify)

24. Some mHealth applications might only be available on certain operating systems (ie iPhones or android systems (eg Nokia, Sony, Samsung)). Would you consider changing your mobile phone for a model that has additional mHealth capabilities?

- ◯ I am an iPhone user and would NOT consider changing to an android operating system
- ◯ I am an iPhone user and would consider changing to an android operation system
- ◯ I am on an android operating system and would NOT consider changing to an iPhone
- ◯ I am on an android operating system and would consider changing to an iPhone
- ◯ I don't know

Other (please specify)

25. Some measurements made using mHealth may take some time to complete (eg lung function measurements or completing questionnaires).

How long would you be willing to spend making measurements using a mHealth system?

- ◯ More than 30 minutes a day
- ◯ 15-30 minutes a day
- ◯ 5-15 minutes a day
- ◯ up to 5 minutes a day
- ◯ 15-30 minutes once a week
- ◯ 5-15 minutes once a week
- ◯ up to 5 minutes once a week
- ◯ 15-30 minutes once a month
- ◯ 5-15 minutes once a month
- ◯ Up to 5 minutes once a month
- ◯ I would not spend any time completing measurements
- ◯ I don't know

Other (please specify)

26. Questionnaires can offer an insight into how you're feeling. These questions often refer to your asthma symptoms and how you're feeling overall.

How frequently would you be willing to complete a questionnaire, which would take approximately 2-3 minutes using an app on your smartphone?

- ◯ I would NOT be willing to complete a questionnaire at all
- ◯ I would be willing to complete a questionnaire daily
- ◯ I would be willing to complete a questionnaire 3-4 times a week
- ◯ I would be willing to complete a questionnaire once a week
- ◯ I would be wiling to complete a questionnaire every 2 weeks
- ◯ I would be willing to complete a questionnaire on a monthly basis
- ◯ I don't know

Other (please specify)

27. mHealth allows reminder notifications to be sent directly to your mobile phone.

Which of the following reminders do you feel would be helpful in managing your asthma: Please tick all that apply

- ☐ Reminders to take your medication
- ☐ Reminders to take your inhaler when you leave the house
- ☐ Reminders to clean your inhaler
- ☐ Reminders to order/ collect a prescription
- ☐ Reminders to make/ attend a GP or asthma clinic appointment
- ☐ Reminders to make lung function measurements
- ☐ Reminders to complete an asthma symptom diary
- ☐ None of the above
- ☐ I don't know

Other (please specify)

28. mHealth allows alert notifications to be sent directly to your mobile phone.

Which of the following alerts do you think would be helpful in managing your asthma? Please tick all that apply.

- [ ] Alerts to indicate that your inhaler is running low
- [ ] Alerts to indicate that you are using your medication too much
- [ ] Alerts to indicate that you have not taken your inhaler
- [ ] Alerts to indicate that you are using in inhaler incorrectly
- [ ] Alerts to indicate your lung function is getting worse
- [ ] Alerts to indicate that pollution levels in your area are high
- [ ] Alerts to indicate that pollen/ allergen levels in your area are high
- [ ] Alerts to indicate that the temperature/ humidity in your area is high/ low
- [ ] None of the above
- [ ] I don't know

Other (please specify)

29. mHealth systems can provide you with feedback and recommendations based on the analysis of various measurements. This feedback may include the suggestion to step-up or step-down your medication or to visit your GP.

If a mHealth system advised you to increase or decrease your medication, would you act upon it?

- [ ] I would NOT accept any recommendations to change my medication from a mHealth system
- [ ] I would accept all recommendations from a mHealth system
- [ ] I would only accept recommendations if the system was endorsed by the NHS
- [ ] I would only accept recommendations if the system provided data and information to support the recommendation
- [ ] I would only accept recommendations if the system was endorsed by my doctor
- [ ] I would only accept recommendations if the system had been scientifically tested
- [ ] I don't know

Other (please specify)

30. What type and level of feedback would you like regarding the results from a mHealth system?

- [ ] I only want alerts/ recommendations if there is a problem
- [ ] I would like to see a summary of my data in graphical form
- [ ] I would like to see a summary of my data explained in text
- [ ] I would like to be able to send data or allow a clinical team to access my data for their feedback
- [ ] I don't know

Other (please specify)

31. We would like to know what support you would like from a mHealth system?

- [ ] I would not like any form of user-support
- [ ] I would like access to health care professionals through the mHealth system
- [ ] I would like access to a pharmacist
- [ ] I would like access/ links to endorsed websites
- [ ] I would like a peer-to-peer online forum, where you can speak to other people with asthma in the UK
- [ ] I don't know

Other (please specify)

32. Some of the devices may cost you money to purchase. We would like to know how much you would be willing to spend on mHealth systems which may help manage your asthma.

- [ ] I would NOT be willing to spend any money
- [ ] I would be willing to spend between £5-20
- [ ] I would be willing to spend £20-50
- [ ] I would be willing to spend £50-100
- [ ] I would be willing to spend £100+
- [ ] I would expect this to be covered by the NHS
- [ ] I don't know

Other (please specify)

33. With regards to privacy and data storage, please indicate which of the following statements you agree with:

- [ ] I would be happy for my data to be stored securely on a database away from my phone
- [ ] I would NOT be happy for my data to be stored securely in any format away from my phone
- [ ] I would be happy for data to be used in an anonymised format for medical research
- [ ] I would NOT be be happy for my data in any format to be used for medical research
- [ ] I would be happy for healthcare professionals to access my data
- [ ] I would NOT be happy for any healthcare professional to access my data
- [ ] I don't know

Other (please specify)

34. mHealth systems often include an element of goal setting. Please choose any of the following statements you agree with:

- [ ] I feel that setting goals would help me manage my asthma better
- [ ] I feel that setting goals would NOT affect my asthma management
- [ ] The interactive nature of goal setting would improve a mHealth system
- [ ] The interactive nature of goal setting would NOT improve a mHealth system
- [ ] a mHealth system should involve incentives to encourage the user
- [ ] A mHealth system should NOT include incentives to encourage the user
- [ ] I don't know

Other (please specify)

35. Do you have any thoughts that you would like to share regarding how mHealth could help you manage your asthma?

Appendix 5: HCP Survey

Managing asthma using mHealth - for health care professionals

Self-management programmes are beneficial for people with asthma to effectively manage their asthma. Despite these beneficial effects, self-management programmes are rarely used. Mobile devices that assist with the management of medical conditions are becoming widely available. This form of mobile technology is termed mobile health or mHealth.

We are a multidisciplinary team that is developing a new mHealth system designed specifically to help people with the self-management of their asthma. The first stage of this process is to determine the opinions of people with asthma and their healthcare team about using mHealth. We aim to use these opinions to create a 'user centred' mHealth system that will better enable people to manage their asthma.

The survey is comprised of 17 questions and should take approximately 5-10 minutes to complete.

By completing this survey you agree for your responses to be used for research purposes. It will not be used in a manner that will allow identification of your individual responses. Anonymised data will be archived in an open data depository in order to make them available to other researchers in line with current data sharing practices.

Many thanks for your time

myAirCoach team

1. Gender

- ◯ Male
- ◯ Female

2. Age (years)

3. Ethnic origin

- ◯ White British
- ◯ White Irish
- ◯ Other White
- ◯ Mixed: White and Black Caribbean
- ◯ Mixed: White and Black African
- ◯ Mixed: White and Asian
- ◯ Other mixed background
- ◯ Indian
- ◯ Pakistani
- ◯ Bangladeshi
- ◯ Other Asian background
- ◯ Caribbean
- ◯ African
- ◯ Other Black background
- ◯ Chinese

Other ethnic group (please specify)

4. Occupation

- ◯ General Practitioner
- ◯ Practice Nurse
- ◯ Asthma specialist nurse
- ◯ Physiologist
- ◯ Physiotherapist
- ◯ Pharmacist
- ◯ Hospital doctor
- ◯ Clinical psychologist

If none of the above, please specify

5. Would you consider yourself an asthma specialist?

- ◯ Yes
- ◯ No

6. Location of practice, first part of postcode (eg E1, SW9 etc)

7. mHealth systems could serve a variety of purposes. Which of the following would you consider a useful purpose of a mHealth system with regards to asthma management?

Please tick all that apply

- [ ] A device/ system that could replace routine (eg annual) asthma check-ups
- [ ] A device/ system that offers advice regarding when additional medical attention should be sought
- [ ] A device/ system to help patient's monitor their asthma over time
- [ ] A device/ system to collect data that patients can show their doctor/ healthcare professional, to demonstrate how their asthma has been
- [ ] A device/ system that detects and alerts patients and/ or healthcare professionals to a deterioration in their asthma control before they would normally notice
- [ ] A device/ system for patients to use as their asthma action plan (provide instructions on how to better manage their asthma)
- [ ] A device/ system to offer educational materials about asthma
- [ ] A device/ system that provides instructions on how to manage their asthma in an emergency
- [ ] A device/ system that can be used to call for emergency help during an asthma attack
- [ ] A device/ system that can take measurements and update a patient's medical record
- [ ] A device/ system that can tell if changes to patient's asthma medication has improved their asthma control
- [ ] A device/ system that can be used for medical trials
- [ ] A device/ system to record treatment side-effects
- [ ] I do not believe a mHealth device/ system would be beneficial to people with asthma

Other (please specify)

8. mHealth systems allow for a variety of information to be collected and stored which could be used by the patient or a healthcare professional to help with the management of asthma. Which of the following information do you think could help your patients achieve better control of their asthma?

- [ ] Information regarding their environment (eg pollution, allergens (pollen), temperature and humidity)
- [ ] Information regarding their lung function (eg peak flow and measurements of airway inflammation)
- [ ] Information regarding their breathing (eg breathing rate and details of how often they cough)
- [ ] Information regarding their heart rate and activity levels
- [ ] Information regarding their stress levels
- [ ] Information regarding their medication adherance
- [ ] Information regarding their inhaler technique
- [ ] Information regarding their diet
- [ ] Information regarding their quality of sleep
- [ ] Information regarding their self-reported symptoms

Other (please specify)

9. mHealth systems allow alert notifications to be sent directly to a patient's mobile phone.

Which of the following alerts do you think would be helpful for asthma self-management?

- [ ] Alerts to indicate that their inhaler is running low
- [ ] Alerts to indicate that they are using their medication too much
- [ ] Alerts to indicate that they have not taken their inhaler
- [ ] Alerts to indicate that they are using their inhaler incorrectly
- [ ] Alerts to indicate that their lung function is getting worse
- [ ] Alerts to indicate that the inflammation in their airways is getting worse
- [ ] Alerts to indicate that pollution levels in their area is high
- [ ] Alerts to indicate that pollen/ allergen levels in their area is high
- [ ] Alerts to indicate that the temperature/ humidity in their area is high/ low
- [ ] None of the above
- [ ] I don't know

Other (please specify)

10. mHealth systems may allow for alerts/ notifications to be sent directly to a patient's healthcare team.

Do you believe it would be useful for alerts to be sent directly to a patient's healthcare team?

- ◯ Yes
- ◯ No
- ◯ Don't know

Other (please specify)

11. Are there specific populations of asthmatic patients who would benefit from a mHealth system?

- ☐ All patients may benefit from mHealth systems
- ☐ No patients would benefit from mHealth systems
- ☐ Mild asthmatic patients may benefit from mHealth systems
- ☐ Moderate asthmatic patients may benefit from mHealth systems
- ☐ Severe asthmatic patients may benefit from mHealth systems
- ☐ Uncontrolled asthmatic patients may benefit from mHealth systems
- ☐ Controlled asthmatic patients may benefit from mHealth systems
- ☐ Newly diagnosed patients may benefit from mHealth systems

Other (please specify)

12. The mHealth system might in theory only be compatible with certain inhaler types that allow inhaler usage monitoring. Would you be happy for your patient to change their inhaler in order to have access to a mHealth system?

- ☐ I would be happy for a patient to change the brand of their inhaler (drug manufacturer)
- ☐ I would NOT be happy for a patient to change the brand of their inhaler (drug manufacturer)
- ☐ I would be happy for a patient to change the type of their inhaler (ie change from a powder inhaler to a pressurised gas inhaler of vice versa)
- ☐ I would NOT be happy for a patient to change the type of their inhaler
- ☐ The decision to change a patient's medication would have to be made on a case-by-case basis
- ☐ I don't know

Other (please specify)

13. Do you think mHealth systems could be integrated into routine asthma care for patients with asthma?

- ◯ Yes
- ◯ No
- ◯ I don't know

Other (please specify)

14. If a patient presented you with data collected on a mHealth device, would you consider this information useful?

- ◯ Yes
- ◯ No
- ◯ Maybe
- ◯ I don't know

Other (please specify)

15. mHealth systems could provide patients with recommendations regarding their treatment based on the analysis of various measurements, in the same way as an asthma action plan. These recommendations may include the suggestion to step-up or step-down their medication or to seek medical advice.

Would you be comfortable with patients following recommendations given on a mHealth device?

- ◯ I would NOT be comfortable for my patients to accept recommendations regarding changes to their treatment from a mHealth system
- ◯ I would be comfortable for my patients to accept recommendations regarding changes to their treatment from a mHealth system
- ◯ I would like to see the data and approve the recommendations prior to any change in their treatment
- ◯ I would like to see the patient in person before recommending any changes to their treatment
- ◯ I don't know

Other (please specify)

16. mHealth systems often include an element of goal setting. Please choose any of the following statements you agree with.

- [ ] I feel that setting goals would help patients manage their asthma better
- [ ] I feel that setting goals would NOT help patients manage their asthma better
- [ ] The interactive nature of goal setting would improve a mHealth system
- [ ] The interactive nature of goal setting would NOT improve a mHealth system
- [ ] A mHealth system should involve incentives to encourage the user
- [ ] a mHealth system should NOT include incentives to encourage the user
- [ ] I don't know

Other (please specify)

17. Do you have any thoughts that you would like to share regarding how mHealth could help your patients manage their asthma?

Appendix 6: Focus group presentation

21/12/2015

mHealth for people with asthma

MY AIR COACH

Focus groups and our aims

A focus group is a form of qualitative research where a group of people are asked their opinions about a product or idea.

We aim to determine **your** opinions of using mHealth for managing asthma

Who are we and what are we doing?

Andrew Simpson, Research Fellow
University of Manchester

Dr Erika Kennington, Head of Research
Jessica East, Research and Involvement Officer
Asthma UK

What is mHealth?

mHealth is the term used for the practice of medicine and public health supported by mobile devices.

Who are we and what are we doing?

myAirCoach is:

- A research project funded by the European Commission
- Aiming to develop a new mobile health (mHealth) to support the self-management of asthma

MY AIR COACH

Focus Group Format

i. Ask you what you *already* know about mHealth for asthma

ii. Provide you with some background information regarding mHealth functions for asthma

iii. Ask you for your opinions on the mHealth functions we have presented

1

21/12/2015

Current use of mHealth

Q1. We would first like to ask what you know about mHealth and asthma, and whether you have any experiences or expectations of using it?

Inhaler technique

Key functions/features
- Sensors detect shaking
- Inhalation flow/pressure
- Timing of activation

Background

A variety of mHealth devices have been produced, some specifically for individuals with asthma and some for more generally use. The functions of these mHealth systems include:

1. Inhaler monitoring
2. Inhaler technique
3. Respiratory rate measurements
4. Prompts and alerts
5. Lung function measurements
6. Symptoms monitoring
7. Environment monitoring (pollen, pollution, temp)
8. Activity and heart rate monitoring
9. Diet and nutrition monitoring

3. Respiratory rate

Key functions/features:
- Breathing rate
- Coughing
- Breathing sounds

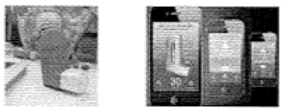
1. Inhaler Monitoring

Key functions/features
- Date and time of inhaler use
- Medication adherence
- Location of usage

4. Prompts and alerts

Key functions/features

Reminders to:
- Take medication
- Collect prescription
- Attend asthma clinic appointments



2

21/12/2015

5. Lung function

Key functions/features
- Spirometry – lung function
- Airway inflammation
  - Exhaled Nitric oxide
  - Breath temperature

8. Activity monitoring

Key functions/features
- Heart rate
- Activity levels
- Calories burnt
- Goal setting

6. Symptoms

Key functions/features
- Symptoms rating
- Impact on quality of life

9. Nutritional feedback

Key functions/features
- Food frequency
- Calorie intake
- Nutritional recommendations
- Goal Setting

7. Environment monitoring

Key functions/features
- Environmental factors may be sent directly to a patient including:
  - Temperature
  - Humidity
  - Air quality (pollution)
  - Pollen count

Question topics

- Measurements
- Burden of inputting data
- Questionnaires
- Alerts and reminders
- Recommendations and user feedback
- User support
- Privacy
- Product design
- Goal setting
- Additional functions

3

21/12/2015

Measurements

The concept of mHealth is to collect physiological, environmental and behavioural data that can be used to provide feedback that may help patients control their asthma.

Q2. What measurements do you think might help you control your asthma or prevent asthma attacks?

Burden of automated data

Some measurements can be collected automatically, which would prevent the need for the patient's involvement. This 'automatic data collection' would usually require the patient to wear and/or carry a device. We would like to know your opinions on this.

Measurements cont.

Q3. There are some additional parameters that haven't been mentioned that could be measured, we would be interested in hearing your opinion of whether you believe these would be useful measures.

Burden of automated data cont.

Q4. Specifically, what are your thoughts on:

i. your inhaler usage and technique being recorded automatically by an inhaler or a device on your inhaler?
ii. the recording of your heart rate and activity levels by wearing a wristband?
iii. your location being measured by your mobile phone to determine location of inhaler usage?
iv. environmental conditions being measured by GPS and/or a wearable device?
v. your breathing rate and sounds being measured via a sensor attached directly to your chest?

Measurements cont.

- Pollution
- allergens
- temperature
- humidity
- spirometry
- exhaled nitric oxide
- breathing rate
- cough counting
- temperature
- heart rate
- stress levels
- activity
- medication use
- inhaler technique
- breath sounds

Burden of lung function measurements

Q5. Specifically, what are your thoughts on measuring:

I. Temperature
II. Nitric Oxide
III. Spirometry

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21/12/2015

Burden of inputting data

To help get accurate information and detect changes in your asthma control some of the measures we've discussed would be required on a regular basis. Some of the measures could be taken 'automatically' and other measurements will require some interaction on the part of the patient – for example completing measures of lung function and inputting the results.

Q6. What are your opinions about taking regular measurements and how long would you be willing to spend completing and inputting the results of these measurements?

Alerts and reminders

Q10. There are additional alerts and reminders that could be sent, and we would be interested in hearing your opinion of them

Questionnaires

Questionnaires offer an insight into how you are feeling. The questions refer to your asthma, your symptoms and how you're feeling overall. We'd like to understand whether you would be willing and, if so, how often you would be willing to give questionnaire feedback via an app on your mobile phone.

Q7. Would you be comfortable providing feedback on your asthma symptoms and how you're feeling via an app?

Q8. What factors do you think need to be considered when designing questionnaires?

Alerts and Reminders cont.

- Pollution
- Pollen
- Dust
- Temperature
- Humidity
- lung function measurements
- medication
- taking questionnaires
- inhaler technique

Alerts and reminders

mHealth allows alerts and reminders to be sent directly to your mobile phone.

Q9. What alerts and reminders do you think would be useful for the management and monitoring of your asthma?

Recommendations and User Feedback

mHealth systems can provide you with feedback and recommendations based on the analysis of various measurements that we discussed earlier. This feedback may include the suggestion to step-up or step-down your medication or to visit your GP.

Q11. What are your thoughts to following mhealth recommendations? Are there reasons why you would/ wouldn't adhere?

Q12. What type and level of feedback would you like regarding the results from the measurements?

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21/12/2015

User-support

As mentioned in the last slide, mHealth technology can provide feedback and advice to patients with asthma based on the analysis of various measurements. We would like to understand what other support you think may be useful.

Q13. What support could compliment the use of mHealth systems?

Product Design

mHealth systems come in various shapes and sizes. We would like to understand your views on how these devices should look and feel and what factors should be taken into account when designing them.

Q17. What design factors would influence whether or not you use mHealth systems?

User-Support Cont.

Q14. If support were available via an online forum, what type of support would you like it to offer?

Goal Setting

Goal setting is a feature often used by mHealth systems. We'd like to understand whether the setting of goals would increase your motivation to use or keep using mHealth system.

Q18. Is it important to have the ability to set, manage and monitor progress against your goals?

Privacy

mHealth systems collect personal and sensitive information. We'd like to understand how you feel about the privacy of the data they collect and how this data should be shared with others.

Q15. What are your thoughts about the privacy of data around using mHealth technology with respect to privacy?

Q16. Are there any groups of people you would or would not like your data to be shared with, for example healthcare professionals?

Additional Functions

Q19. Are there any additional functions or features that you would like to see incorporated into mHealth systems?

6

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