A fresh look at designing respiratory health devices

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Summary

Many pharmaceutical companies see equivalence claims as the fastest and most cost effective route to market for new respiratory drug devices. In reality though, the process is often not as simple as first thought. By their very nature, equivalence claims mean adopting existing, often old, technologies and user interfaces. Furthermore, the task of demonstrating equivalence can be protracted and expensive. Thus, in many cases, manufacturers are left accepting sub-optimal devices, with known usability issues. Moreover, opportunities may be missed to explore different products, technologies and services that would improve usability, compliance, patient satisfaction and market share. This paper uses tools from the discipline of human factors to explore what a fresh approach to requirements capture and design might mean for devices designed from first principles.

A structured approach is described for designing medical devices based on patient and stakeholder information requirements. The approach is based on the premise that better designs are informed by an explicit understanding of what information is required, where and when, along with an understanding of who needs it and how it should be presented. These information requirements are explored at the earliest stages of the design process and revisited throughout the design.

Introduction

Ostensibly, decision making is at the heart of the safe and effective management of respiratory health. By exploring key decision points, it is possible to reveal rich insights into patient life. Opportunities can be identified for better ways of communicating with the patient and key stakeholders. Decisions relating the control of patients' environments and the use of their medication will influence both their symptoms and their quality of life.

Experimental methods

There have been many attempts to model the decision making activity. Most approaches involve some form of observation of information, orientation to the current situation, a choice as to which action to adopt, and finally an action. The decision ladder [1] (see Figure 1) is a representation of this decision cycle commonly used within an analysis approach used in human factors called Cognitive Work Analysis [2].

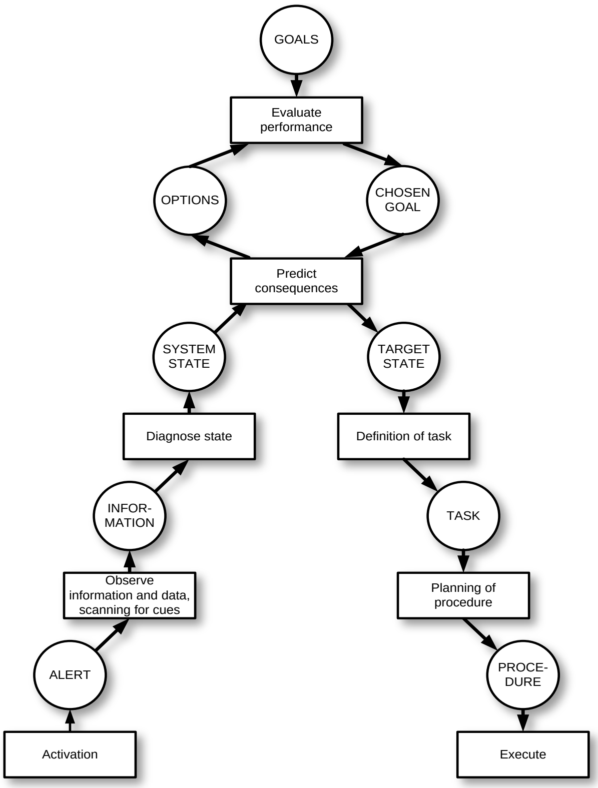


Figure 1 - the decision ladder model

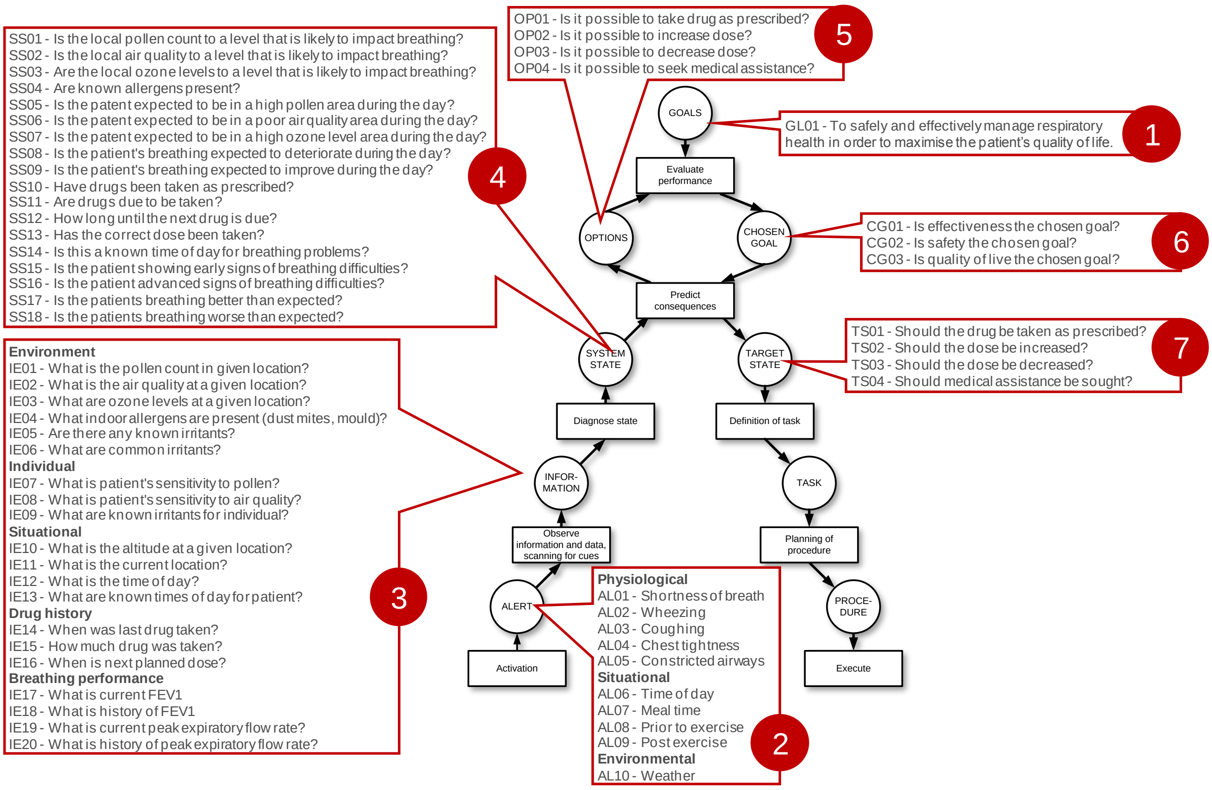
Unlike some of its counterparts, the focus of the approach is on the entire decision-making activity, rather than the moment of selection between pre-examined options. The model generated around the decision ladder is not specific to any single actor; rather it represents the decision-making process of the combined work system. In many cases, the decision making process may be collaborative and distributed between a range of human and technology-based decision-makers.

As illustrated in Figure 1, the ladder contains two different types of node: the rectangular boxes represent data-processing activities, while the circles represent resultant states of knowledge. Novice users (to the situation) are expected to generally follow the decision-ladder in a linear fashion. When followed linearly, the process starts with some form of activation (on the bottom of the left leg). Following the path of the arrows in Figure 1, observations are then made, and information elements collected. These information elements are then combined to determine a system state. Options are then formulated and evaluated against goals. Based on an understanding of the situation, a context specific goal is chosen and target state selected. A task is then defined and broken down into a procedure, which is finally executed. Thus, the left side of the decision-ladder represents the observation of the current system state, whereas, the right side of the decision-ladder represents the planning and execution of tasks and procedures to achieve a target system state. Expert users, familiar with the situation, are expected to link the two halves of the ladder by shortcuts. In familiar situations, users are expected to recognise an appropriate task after collecting information from the system, negating the need to explicitly consider different options and evaluate them against goals.

The approach described in this paper has been successfully applied in the past to design new interfaces for a variety of products including examples as complex as the design of radiography equipment [3] and unmanned air vehicles [4].

Results

The approach for eliciting the systemic information requirements is based on a series of semi-structured interviews with system experts and/or stakeholders. The process is detailed in Table 1. Information is collected and captured around the structure of the decision ladder (see Figure 2). The model in Figure 2 is normally constructed by taking a single pass through the decision making process based on the most common alerts, information elements, system states and options. This is often based on a real world situation that is being recalled by someone with first-hand experience of the process (normally a patient or a healthcare professional). Once this first pass has been completed, the model can be expanded by revisiting each box in turn with the interviewee and questioning, what else is missing from the model, such as, what other things might be used as an alert?, or what other information elements are there?



SS01 - Is the local pollen count to a level that is likely to impact breathing?
SS02 - Is the local air quality to a level that is likely to impact breathing?
SS03 - Are the local ozone levels to a level that is likely to impact breathing?
SS04 - Are known allergens present?
SS05 - Is the patent expected to be in a high pollen area during the day?
SS06 - Is the patent expected to be in a poor air quality area during the day?
SS07 - Is the patent expected to be in a high ozone level area during the day?
SS08 - Is the patient's breathing expected to deteriorate during the day?
SS09 - Is the patient's breathing expected to improve during the day?
SS10 - Have drugs been taken as prescribed?
SS11 - Are drugs due to be taken?
SS12 - How long until the next drug is due?
SS13 - Has the correct dose been taken?
SS14 - Is this a known time of day for breathing problems?
SS15 - Is the patient showing early signs of breathing difficulties?
SS16 - Is the patient advanced signs of breathing difficulties?
SS17 - Is the patients breathing better than expected?
SS18 - Is the patients breathing worse than expected?

OP01 - Is it possible to take drug as prescribed?
OP02 - Is it possible to increase dose?
OP03 - Is it possible to decrease dose?
OP04 - Is it possible to seek medical assistance?

GL01 - To safely and effectively manage respiratory health in order to maximise the patient's quality of life.

CG01 - Is effectiveness the chosen goal?
CG02 - Is safety the chosen goal?
CG03 - Is quality of live the chosen goal?

TS01 - Should the drug be taken as prescribed?
TS02 - Should the dose be increased?
TS03 - Should the dose be decreased?
TS04 - Should medical assistance be sought?

Environment
IE01 - What is the pollen count in given location?
IE02 - What is the air quality at a given location?
IE03 - What are ozone levels at a given location?
IE04 - What indoor allergens are present (dust mites, mould)?
IE05 - Are there any known irritants?
IE06 - What are common irritants?
Individual
IE07 - What is patient's sensitivity to pollen?
IE08 - What is patient's sensitivity to air quality?
IE09 - What are known irritants for individual?
Situational
IE10 - What is the altitude at a given location?
IE11 - What is the current location?
IE12 - What is the time of day?
IE13 - What are known times of day for patient?
Drug history
IE14 - When was last drug taken?
IE15 - How much drug was taken?
IE16 - When is next planned dose?
Breathing performance
IE17 - What is current FEV1
IE18 - What is history of FEV1
IE19 - What is current peak expiratory flow rate?
IE20 - What is history of peak expiratory flow rate?

Physiological
AL01 - Shortness of breath
AL02 - Wheezing
AL03 - Coughing
AL04 - Chest tightness
AL05 - Constricted airways
Situational
AL06 - Time of day
AL07 - Meal time
AL08 - Prior to exercise
AL09 - Post exercise
Environmental
AL10 - Weather

Figure 2 - The decision ladder model annotated for respiratory health with example alerts, information elements, system states, options, goals, chosen goals, and target states (large numbers relate process steps in Table 1)

Table 1 – Process for eliciting information requirements for respiratory health (stage numbers relate to numbered circles in Figure 2)

Stage 1 – Determining the goal The process starts near the top of Figure 2. The goal at this stage of the process is simply *‘To safely and effectively manage respiratory health in order to maximise the patient’s quality of life.’*
Stage 2 – Alert Moving to the base of the left leg of Figure 2, possible alerts that may indicate a change to the system state include physiological states such as shortness of breath, wheezing and coughing. Likewise, other alerts may be linked to situational aspects such as the time of day or a meal, or the relationship to exercise. Finally, other alerts might also be liked to environmental factors like the current weather.
Stage 3 – Information The information elements are the ‘nuggets’ of information that can be brought together to understand the state of the system. In this case, they include information about the physical environment (e.g. pollen count, air quality), the individual patient (known irritants), the given situation (e.g. time of day, location), drug usage (e.g. when taken, how much) and breathing performance (e.g. FEV1, peak expiratory flow rate).
Stage 4 – System state The system states represent a perceived understanding of the system based upon the interpretation of a number of different information elements. Questions such as *‘is the pollen count to a level that is likely to impact breathing?’ c*an be assessed by considering a number of different information elements together. In this case, the current pollen level and the patient’s sensitivity to it.
Stage 5 – Options At a high level, in this part of the decision making process there are four main options available to the operator: Is it possible to take drug as prescribed? Is it possible to increase dose? Is it possible to decrease dose? And Is it possible to seek medical assistance?
Stage 6 – Chosen goal The chosen goal, at any one time, is determined by selecting which of the constraints receives the highest priority. For example is the priority at the given time, effectiveness, safety or quality of life.
Stage 7 – Target state The target states mirror the option available (see stage 5).
Stage 8 – Task The tasks relate to the specific actions required to achieve the chosen goal. They are outside the scope of this paper.

While each of the aspects of Figure 2 informs the design process, the left leg of the model is expected to be the most useful in understanding the information requirements for a medical device. There is an interlinked relationship between the alerts, information elements and system states. Information elements are expected to direct the identification of system states; likewise, as new system states are identified in the model, this often leads to the inclusion of additional information elements which, in turn, might identify new system states.

The model is particularly useful for identifying information elements that users rely on but they often fail to articulate, such as changes in the weather. One useful approach for building the model and identify additional alerts, information elements and system states, is to question what the interviewee would you do if each of the identified element were missing. As with all theoretical models, there is challenge in identifying a suitable stopping rule – that is how many information elements should be included in the model, particularly when their relevance can be questioned. Ultimately, this is down to the analyst to determine.

Once the model is considered to be complete, the list of alerts, information elements, system states and options provides a comprehensive description of ‘what’ information may be required to support decision making. This list is deliberately independent of context and thus represents the totality of what might be useful to know. The next stage of the process is to code this list to indicate when the information may be needed (e.g. first thing in the morning, prior to drug taking, during drug taking, after drug taking), where it could be displayed (e.g. on the device, on an IFU, on packaging, on a companion app, via a healthcare professional, on a website), to whom (e.g. the patient, a carer, a healthcare professional, a pharmacist, a prescriber) and finally ‘how’ (e.g. text, photos, graphics, video, audio files). Logistically, this is best done by converting the model to a tabular format, adding columns for each possibility and coding the matrix accordingly. The generated table can then be interrogated to establish if the constraints on the system are appropriate. Cells that are not coded may represent particular opportunities for product improvement.

Discussion and conclusions

For complex systems, a structured approach is needed to ensure firstly, that all the required information elements are considered, and secondly that they are included in the optimal way to ensure an appropriate balance of system values (e.g. safety, efficacy, efficiency, usability and resilience).

The approach described in this paper provides welcome structure to the process of eliciting and exploring information requirements that focus on end users and stakeholders decision making needs. One of the clear strengths of the approach is that it provides a very explicit link between the data collection, the analysis, and the resultant design that can be revisited and audited throughout the design process.

Informed decision making is fundamental to safe management of respiratory conditions. There is a long established connection between the information available to decision makers and quality of decision making. This does not necessarily mean presenting more information; on the contrary, too much information can be as detrimental to performance as too little. Rather, to optimise system performance (e.g. safety, efficacy, efficiency, resilience), effective decision making must be supported by the right information, at the right time, in the right place, to the right actors, in a format that can be readily understood.

The approach can be applied to existing designs as part of the equivalence process; however, it is contented that applying it at the earliest opportunity in the design process would allow better designs to be identified and explored.

In the case of respiratory health, the approach highlights that the use of medication is impacted by a wide range of factors distributed across the environment, the individual, the given situation, the history of drug use and breathing performance. It is contended that better consideration and integration of this information could lead to better management of respiratory health. The approach does not directly leap to a solution (such as an app), rather it systematically questions the different option for, when, where, how and to whom the given information should be displayed.

References

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