GENERATIVE PARTICIPATORY DESIGN FOR INTERACTIVE MEDICAL DEVICES

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1. Introduction

User centred design (UCD) is a design philosophy that puts the user at the centre of the design of a system, service or product. This is being championed by both the Industrial Design and Human Computer Interaction (HCI) communities. The emphasis on the needs of the user, as opposed to the product, is a fundamental change to the approach of design [Boztepe 2007]. The way in which the user is involved can range from inclusion at specific points in the design process, for example specification requirements and user trials, to inclusion as part of the design team for the entire process, known as Participatory Design (PD) [Ehn 1988]. UCD is both a broad philosophy and a variety of methods [Abras 2004].

Designers are rarely typical users [Thimbleby 1991], [Norman 1998]. This is especially true for specialist medical devices, for which the designer can seek to understand the context of use, but they are highly unlikely to be the primary intended user. Even for a product for which the designer might be the end user, such as a mobile phone, the skills and interests of the designer will rarely be ‘typical’, with a likely skew towards a ‘lead user’ [Von Hippel 1986] or ‘early adopter’ [Rogers 2010]. This can lead to products which do not meet fundamental usability requirements which, in the case of some medical devices, can have significant health outcome implications. Recognising the importance of product usability, medical device manufacturers in particular are accustomed to the inclusion of users in their design process through user trials, but there is traditionally little formal inclusion of UCD methods at an earlier stage.

The UCD process recognises that the people who will be using the products (or services) have a better understanding of what their needs, goals and preferences are. It is the designers’ role to elicit this information by involving users at every stage of the design process [Saffer 2010]. Rudd et al. [1996] agree, saying that users do not know how to articulate their requirements (since much of their relevant knowledge is tacit and not accessible to conscious thought), therefore verbalising their requirements is subjective to previous experience [Blackler 2009].

A user centred approach advocates considering user needs from the earliest stages in the process. New design philosophies advocate an iterative design process where designs are trialled continuously through building prototypes, learning from the prototype to inform the design process and move the design forward [Buxton 1980]. The cycle of design, prototype and evaluate is used repeatedly throughout the iterative process providing a variety of opportunities at which to involve potential users.

Steen [2007] regards Human Centred Design (a term often used interchangeably with UCD) as an umbrella term for all processes integrating the final user. Both Scariot [2012] and Steen acknowledge that definitions of design research techniques are loose and can be contradictory, instead recognizing that a mix of techniques will be used where methods are selected to suit the required output. A review of literature reveals a host of tools and techniques that can be utilised during the design process for a variety of needs. Hare [2014] attempts to classify them according to their use within the design process; generative research methods gather new data directly from the user, interpretation methods interpret that data into a form that can be discussed within the project team, specification methods capture the data in a more formal document, ideation techniques realise a concept and finally, user trials enable conversations with the user around a realised concept.

This paper covers the application of UCD at the earliest stages of the design process often referred to as the 'fuzzy front end' [Kim and Wilemon 2002], where few design decisions have been, or can be, defined. Here 'generative' research approaches can be applied to create new ideas or concepts -not necessarily of the final product but which can be used to better understand user needs and desires. Generative research methods can be divided into four categories [Saffer 2010]; observational methods are used to observe what people do in a 'conscientious' manner, interviews involve talking to people, activities enable the designer to engage with an artefact alongside the user and self-reporting techniques are for the user to capture their own thoughts and activities without a researcher present.

Kaulio [1998] defines three levels of user involvement; design for users, design with users and design by users. In this context, human centred approaches are considered 'design for users' whilst participatory methods facilitate 'design by users' [Sanders and Stappers 2008]. Participatory approaches take a democratic view on design where users get equal or even weighted opinion and control. Users are considered as 'experts of their own experience' and the designer becomes a facilitator [Scariot 2012]. Games and activities are utilised to make the process accessible and fun [Sanders 2010], four main purposes of these activities are defined as; 1) Probing, 2) Priming (to immerse the user in the domain of interest), 3) Understanding (experiences) and 4) Generating (ideas or concepts).

Participatory design approaches include two-dimensional collages, three-dimensional mock ups, card sorting and envisioning using pre-prepared materials. Users organize pictures, words, and tangible objects from paper-based and online sources to create collages. Sanders [2010] describes the use of collages in participatory design to probe for existing knowledge, to prime participants in the area of interest, to understand viewpoints, motivations and emotions and to generate ideas. Card sorting is a fast, easy and low cost activity that is well suited for the early stages of the design process [Vredenburg 2002]. Typically, participants are given a variety of items (images or words) on individual cards and are asked to repeatedly categorize the items according to criteria.

For companies employing a PD approach, it is value-adding both in terms of improved design output (leading to greater commercial success) and in considering the overall experience of product/service interaction for the user. For medical device companies, it is an increasingly important tool that enables them to comply with necessary regulatory frameworks and significantly reduces the risk of developing services that do not meet the market needs.

However, translation of user needs into an interface specification still relies on the designer. For our study, we required a repeatable approach where users are able to design an interface within parameters already identified through the more traditional UCD approaches. This paper discusses the application of a UCD approach in the early stages of two projects. Within this approach a novel PD technique is presented.

1.1 Interaction design

The interface of a device provides the link between the user and a product's functionality [Frens 2006]. Interactive prototypes can be used throughout the design process with early stage prototypes employed to gain a clear conceptualization of the basic issues of the design, whereas the later stage prototypes are used to establish the technical feasibility of the product [Pugh 1991].

To incorporate interaction in a prototype the model needs to be responsive to a user's action, or at least give an appearance of being responsive. Toolkits and methods range from two-dimensional screen-based techniques and 'faking' the feedback of the product, to techniques making models truly interactive through the addition of electronic modules in the prototypes to "deal with time, phrasing and feel" [Buxton and Sniderman 1980].

Low fidelity techniques which fake interactions can produce extremely powerful experiences. These methods can be extremely quick and low cost but will often require facilitators to act as the 'computer'.

Paper prototyping [Snyder 2003] uses sticky notes or screen sketches to represent the on screen functions of the product. The user interacts directly on paper, or a physical mock-up of the form (for example a foam model), and the facilitator will adjust the screens depending on how the user interacts with the product. The very nature of a paper prototype invites the user to give feedback on fundamental issues of the design [Boling and Frick 1997], [Holtzblatt 2005]. The low fidelity nature of the prototype means that interactions can be modified during studies according to user feedback. There are several examples of the use of paper prototypes in literature [Virzi 1996], [Liu and Khooshabeh 2003], [Sefelin 2003], [Blackler 2009], [Hare 2009], [Sauer and Sonderegger 2009], these use paper to convey the design of the interface encouraging users to feedback on the system as a whole. However, no examples of paper prototyping can be found that support users in designing an interface.

Later in the design process 'smart' prototypes can be used which respond directly to users' interactions. They require some form of electronics to be integrated into their physical form which directly control the digital functions of the prototype. However, interactive prototypes are more costly to implement (both in the materials and time) and convey a higher level of fidelity to the user.

1.2 Commercial medical device considerations

Medical devices are subject to complex regulations to ensure safety of use. It is the responsibility of the device manufacturer to ensure conformity. In Europe, ISO 62366 covers the usability of medical devices and describes a 'usability engineering process'. One of the recent shifts of this standard is from 'user error' to 'use error', a subtle but important change of responsibility for errors from the user to the device. This standard has been integrated into medical device design for a number of years and medical device manufacturers are accustomed to design processes that involve the user. However this is predominantly through user trials which evaluate the usability, as opposed to the suitability, of an interface.

2. Introduction to the projects

This paper presents two projects which use generative PD tools within a commercial medical device design context. A UCD approach was taken for both projects and the activity described in this paper is part of the wider process. Both projects required user involvement at a very early stage to provide information before any expensive digital interactive prototype effort was committed. Users of devices in both projects are specialists (such as surgeons and clinicians) who will have extensive training before operating the devices. Typical user involvement at this early stage are observation and interview based, however translation of user needs into an interface specification still relies on the designer. We required a repeatable approach that allowed users to design an interface within the parameters identified through the more traditional UCD approaches. These 'designs' could be analysed to form a better understanding of user needs (both observable and latent needs).

The projects had reached a stage where information needed to be gathered about the type and value of data on screen, what needed to be seen and where it should be. Potential information to display had previously been gathered through observation sessions and semi-structured interviews.

2.1 Project 1

The first project is the User Interface (UI) for a specialist monitoring device. The company was designing a new monitor which included a touchscreen, something they had never done before. In addition, new features were included that allow clinicians to record and review data plus further data interrogation capabilities. Sensors produced data that could be viewed both as numeric values and in graphical format. Data on screen included:

- Patient data
- Continuous sensor data - up to 6 different sensors could be attached
- Momentary data - up to 2 data sources could be attached
- Data manipulation capabilities

2.2 Project 2

The second project presented is the design of the interface and workflow for a Patient Specific Implant

(PSI) Computer Aided Design (CAD) software package. Currently the digital PSI design process relies on shared understanding and close collaboration between key stakeholders (such as design engineers and surgeons), therefore, the purpose of this software was to automate some of the more complex functions, in turn reducing the level of specialised skill required to operate the software and increasing accessibility to healthcare professionals within hospital environments. The stage of the project described here involved the design of the software's interface and workflow utilizing a PD approach.

3. The broad UCD process applied

The next section focusses on the point the design process moves from informative involvement, where the user was seen as a source of information, to participatory involvement, where design was conducted by the user. Informative involvement uses techniques such as interviews, questionnaires, focus groups and observation; the designer collects information considered necessary for project development. Participatory involvement utilizes the techniques of experience exchange and idea generation (e.g., storytelling workshop, card sorting, brain-drawing, journals, etc.).

The study for project 1 was completed in 2014 and project 2 was conducted in 2015.

3.1 Project 1 - monitoring device

The general UCD approach for project 1 was:

1. Context & Direction including: Analytical Review, Semi Structured User Insight Interviews and Ethnography, Benchmark Usability Study, User Interface Design Specification, Mapping and Review Workshop
2. Conceptual UI design -creating an outline structure for the UI.
3. Formative Usability testing - paper prototyping (described in this paper)
4. UI design Development
5. Formative Usability testing -interactive prototype
6. Final visual development and handover

This project was positioned in a wider design process of the company who commissioned the work. The work presented here falls within the first round of formative usability testing. Due to the medical training required to operate the device it was decided to use the user trials to explore two different fundamental concepts for structuring the interface ('top heavy' and 'bottom heavy'). The 'top heavy' concept allows interaction to be performed directly on the data it concerns, for the 'bottom heavy' concept all interaction is conducted through menu buttons.

The goal of the study was to evaluate user preferences and usability implications of early concepts through the use of low fidelity prototypes alongside informal interview and participatory design tasks.

Specifically the assessment focussed on:

1. The ability for users to navigate menu structures and graphical UI architecture, focussing on expectations, desires and preferences.
2. Thoughts and opinions relating to the visual appearance.
3. Understanding the vital data and functions accessible through the home screen of the device.
4. General opinion, expectation and desires on the new monitoring system.

At this stage, the scope of the study was limited to the usability of the user interface and did not include an evaluation of usability relating to the physical design itself.

With this paper we are focusing on the participatory design element which sought to improve understanding of the vital data and functions accessible through the home screen of the device (point 3 above). This section is included to understand the context of the study.

3.2 Project 2 - specialist medical software

The wider UCD approach for project 2 was:

1. Gathering user needs; Semi Structured User Insight Interviews
2. User trials - Paper prototyping - generation of; GUI architecture, workflow content and structure (described in this paper)
3. Development of User Experience (UEx) Concepts; Software appearance, colour schemes, icons
4. User trials -Interactive prototypes

5. On-going Software Development; Software Design Specification

Additive Manufacture for Design-Led Efficient Patient Treatment (ADEPT) is a 3 year project that focusses on advancing the use of design and 3D printing technologies within cranio-maxillofacial facial surgery. The project is funded by the UK's innovation agency, Innovate UK and the Engineering and Physical Sciences Research Council (EPSRC). It involves 4 partners; 2 from industry (Renishaw Plc & LPW Technologies), a university (PDR at Cardiff Metropolitan University) and an NHS Trust (ABMU HB).

The work discussed is part of the first round of user trials which aimed to identify user expectations and anticipations of the appearance and operation of the software. The study involved the creation and trialing of early stage paper prototypes of the software's UI focussing on user interactions, preferences and expectations of the software's layout and proposed functions.

4. Participatory design - the jigsaw puzzle activity

The approach used was to combine participatory collaging techniques with paper prototyping methods and integrate it into our existing UCD process, this resulted in a design study we refer to as the 'jigsaw puzzle' activity.

The jigsaw puzzle approach allows each participant to design their own interface. The interface can be assembled in paper format from individual screen elements in the same manner that a jigsaw is constructed. Screen elements are mocked up, printed out and cut into dedicated blocks for the participant to then chose the most appreciate 'jigsaw pieces' to create an interface that they would like to use. With this approach different configurations of data can be explored such as the size of each component, interaction styles and the importance of content holders. This approach can be applied to a whole screen or sections of it. The task is completed with a facilitator who encourages conversation through the 'think aloud' protocol [Lewis 1982]. This approach aims to encourage high level feedback to identify what data should be shown, where and how it could be interacted with and other fundamental design considerations. It is intended to be conducted prior to traditional user testing techniques which explore more detailed issues such as colour, font size and contrast through an iterative cycle.

Figure 1 shows a small selection of the screen elements for project 1, each of these was cut out separately so that the user can create their own interface.

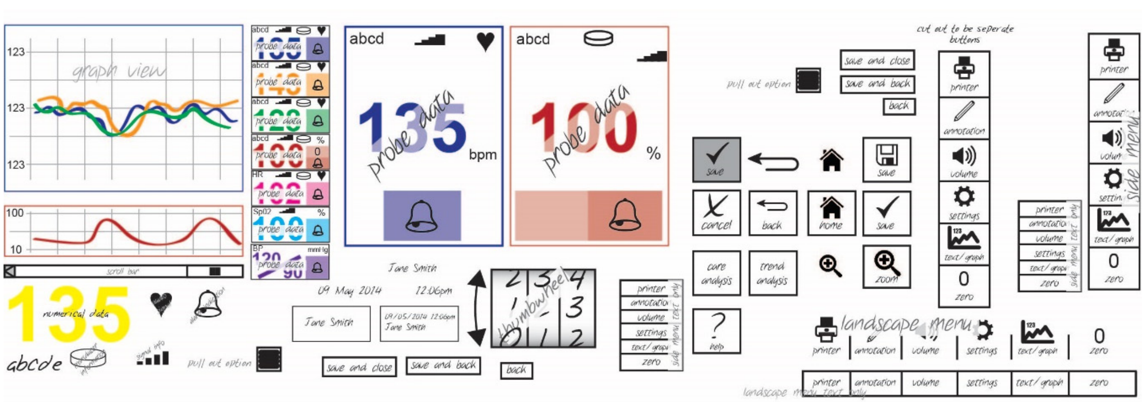

Figure 1. A small selection of the screen elements for project 1 -each element was cut out separately so that the user could create their own interface

5. Project 1 –interface of a patient monitor

The aim of the jigsaw puzzle study was to investigate two early user interface ideas developed for a patient monitoring device. The purpose of conducting this study was to inform and guide future design and development activities relating to the UI, aiming to identify usability issues at a point within the design process that changes can easily be made, therefore reducing risk.

5.1 Study design -general

8 participants were recruited who were all typical users of the type of monitoring device being developed. The study was a one to one interview in which participants worked through a series of scripted tasks, relating to on screen data and frequently used functions. The structure of each session was:

1. Introduction to the study
2. Introduction to the interaction concepts
3. Discussion on visual direction
4. Jigsaw task
5. Test scenarios
6. Semi-structured interview

Parts 1- 3 are ‘priming’ tasks which ensure all participants had the same understanding of the project. Part 4, the jigsaw task is the focus of this paper and will be covered in more detail in the next section. Part 5 asked participants to complete a series of scripted scenarios adopting a 'think-aloud' protocol, explaining their expectations and desires. Part 6 finished off the session capturing any extra information in a semi-structured manner.

5.2 Study design -the jigsaw puzzle task

The task was broken down into two parts, the first to design the complete home screen and the second to design the contents of one data container (used to show up to 6 different types of information).
Participants were presented with various options for home screen data, menu systems and data containers, they were asked to choose and arrange their preferred options. The prototype consisted of around 70 individual paper ‘jigsaw pieces’ for each participant to select from and create their desired screen, these were not exclusive so if the participant wanted a different option then this could be drawn up in the session (blank paper was included for this). The individual pieces focused on content, interaction style and size rather than graphical design elements. For example, the monitor has multiple sensors which can produce 6 real-time data sets in certain configurations; each was mocked up to allow the user to determine their relative value. In addition, options for 'help' and 'zoom' were offered to promote conversation about need as opposed to execution. At the end of the session questions were asked to uncover any data felt to be missing.

5.3 During the study

Participants were able to fully engage with the task, initially we provided a blank screen to represent the size of the touch screen specified to us. However, it became apparent that this limited participants' ability to configure the screen to their needs. With the paper-based approach individual elements could overlap or be placed in positions not normally possible.

5.4 Results

Each study was video and audio recorded, in addition the screen and data container designed by each participant was photographed. The data was collated and compared to produce a summary of findings. Three of the screens constructed by participants are shown in Figure 2.

Figure 2. Three screen designs by participants (note that elements of the design have been removed for confidentiality)

5.4.1 On screen data

Participants always selected graphical data first for the primary data sets, highlighting the importance of seeing the data over time.
Nobody selected solely 'numerical view' elements (despite the industry norm to be numercial).
There was varied opinions about what additional data should be on screen. Some people selected specific additional data while others designed it to be hidden into a menu system or just pop up when the spot measurements were taken. There were discussions around ranking the value of the data sets which can be compared across participants. Size wise everyone felt that the main data graphs should be considerably larger than any other piece of data.
One data set was felt to be missing.

5.4.2 On screen menu system

- 5 people had a landscape menu layout (always at the bottom)
- 3 people had a portrait menu layout (always to the left)
- 3 people chose to have the menu as a 'pull out' option
- 6 chose to have their scroll at the bottom of the two graphs rather than in the middle (or anywhere else).

5.4.3 Help and zoom

The majority of users saw no use in a zoom button. Two participants indicated that it would negatively affect the graphical view as they are accustomed to seeing it at a particular scale.
Two users did see value in the zoom. One participant indicated that it would help to understand the finer details of the data. The other participant felt that it would be the equivalent of an 'expert mode' as it would remove all the information from the screen and allow for a larger view of just the two main graphs.
Only one participant was enthusiastic about the prospect of industry protocols as a help button. Some participants were actively against it saying that it may cause problems with people relying on them and because everything is so contextual this could cause a negative outcome.

5.4.4 Data containers

Generally participants all produced that same design for the 'data container'.
Participants who currently use alternative systems were confused by one icon used.
Some participants felt that the sensor type was not necessary because the difference between the two sensors can be determined at an audio level.

5.5 Outcomes

The jigsaw puzzle approach was an engaging way to elicit user needs where users have extensive training in their specialism. Specifically this task aimed to explore the data and functions accessible through the home screen of the device. The results provide evidence for the future development of the interface in line with regulatory requirements of medical devices.

6. Project 2 – PSI design software interface

The aim of the study was to identify user expectations and anticipations in terms of the appearance and operations of a new software platform intended to design two specific types of cranio-maxillofacial PSIs.

6.1 Study design - general

9 participants were recruited who reflected the range of users of the type of design software being developed; these were 2 surgeons, 4 prosthetists and 3 trainees. The study consisted of four 1:1 sessions and two group sessions of 2 and 3 participants due to time constraints and commitments. The structure of each session was:

1. Introduction to the study

2. Brief background interview - to assess the participants' familiarity with PSI design and their use of 3D CAD software
3. Jigsaw puzzle activity - participants were asked to create their ideal UI layout based on intuition and any existing understanding of how such systems operate.
4. Task simulation – participants asked to interact with their designed UI layout to follow an implant design process

6.2 Study design - the jigsaw puzzle task

A similar approach to that used in project 1 was used. Participants were asked to use a blank sheet of paper, and a number of pre-prepared post-it notes representing typical functions or elements of the UI to create their ideal layout based on intuition and experience of using existing software. Users were able to edit these elements or create additional content using marker pens. As in project 1, the individual pieces again focused on content, interaction style and size rather than graphical design. For example, an element representing the view of the main 3D model could be placed anywhere on screen and allocated as much space as the participant deemed necessary.
Participants were then asked to use their designed UI layout to follow a theoretical implant process based on a workflow developed earlier in the project. They were asked to 'think aloud' and describe their thought processes and actions at each stage along the process, as well as their opinions on the order and content of the workflow.

6.3 During the study

All participants were able to fully engage with the jigsaw puzzle task to create their ideal UI layout. In the majority of sessions the task simulation activity turned into an extended discussion providing a number of key insights into the content and order of the workflow and the expectations participants had regarding some of the proposed functions. Using the jigsaw puzzle as a paper prototype in this way also allowed participants to edit the layout of the UI at various points along the process workflow.

6.4 Results

As in project 1, each session was video and audio recorded, and the paper prototypes designed by each participant photographed. The data was collated and compared to provide a number of design recommendations for the software development team to consider going forward. The main recommendations were:

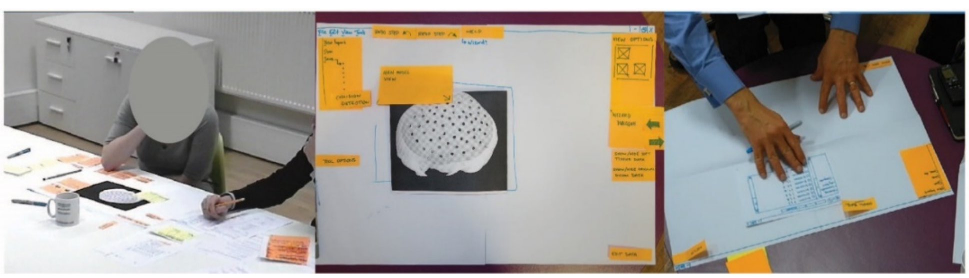

Figure 3. Images from the jigsaw activity user trial

6.4.1 Simplicity

Participants suggested making the software interface as simple as possible would increase the overall usability of the package. Any symbols used should be easily recognisable and the help menu should be written in clear, understandable language, avoiding the use of technical 'jargon'. It was also recommended that the help menu should feature visual references to aid communication.

6.4.2 Easily recoverable cases

One concern that was often raised by participants was that progress is often lost too easily when using CAD and other similar software packages. This could be avoided by making sure cases are easily recoverable by either reminding the user to save progress often or by including an autosave feature, thereby removing the need to manually save altogether. Based on participant responses, it was also recommended that undo/redo functions are very accessible and that it is easy to retrace steps and reverse/alter design choices earlier on in the process.

6.4.3 Degree of automation

Whilst it was largely agreed amongst participants that automatic features would be beneficial, it was often suggested that an ability to manually edit and make adjustments to automatically designed features would provide a level of reassurance.

6.4.4 Hard tissue feedback

It was suggested that the software should contain some form of accurate collision detection between the implant being designed and the hard tissue (bone) interface. It was also suggested that any areas of intersection between implant and anatomy should be highlighted, possibly with the use of colour. It was also recommended that the software should convey the quality and suitability of bone for screw retention at fixation sites, also through the use of colour.

7. Conclusion

In both projects, the jigsaw approach generated valuable data concerning what the user wanted, and expected to see, on screen. By taking a participatory approach the designers were able to fully explore the relevance of information to be used by a specialist in a niche product area. During the studies participants felt able to fully engage with the task with minimal guidance and no prompting from the facilitator allowing the session to be an unbiased creation of what the user would like to see on screen. For the patient monitoring project especially, it was felt that the session 'opened up' the participant to be more creative when going through the subsequent parts of the user session.

In a majority of sessions the jigsaw activity promoted a lengthy 'conversation' with the user. Whilst this can be a really useful way to have a focused conversation, some of the users in project 2 found it tiring and it became difficult to engage them for the full duration of the exercises. Another possible limitation of the approach is demonstrated by a comment received in project 1: “It seems strange to design it just for me, I know others will want something different, maybe it should have a personal login and style?”. This could suggest that the approach might bias users to designing an editable interface.

Overall, the jigsaw puzzle activity proved to be a very efficient way to involve the user in a participatory design element of the design process, in both the set up effort and in the quality of results achieved. From a set up point of view the jigsaw puzzle activity was a fast, highly portable, infinitely adjustable and straight forward approach to designing, and interacting with, a potential interface. It created the feeling of going through a software interaction, assisted with a personal approach that yielded conversation and as a consequence, detail that may not have been captured by other methods.

The approach enabled the user to create interfaces and interactions not possible in other formats; users were not constrained by technical capabilities, size or any preconceived ideas of the designers. From the designers point of view it allows people without programming skills to become involved with the construction and flow of the interface at a very early stage. The approach was able to create a robust foundation for a detailed software specification document to inform the development of higher-fidelity software prototypes.

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