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Open Design and Medical Products: Irreconcilable Differences, or Natural Bedfellows?

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Abstract

This paper describes the first case study of a continuing practice-based PhD as a work-in-progress, exploring the benefits of open design in the conception (and development) of medical products. Described here is the first attempt to tackle some of the issues facing the implementation of open design in a field where a recognised move to 'open' working practices & innovation is needed. Presented are some initial results, and some analysis that (it is hoped) will provide an opportunity for discussion.

There are moral and pragmatic reasons to include people in the design process, especially true for medical products- whatever their complexity. Some people cannot participate in traditional collaborative design workshops (through suppressed immune systems, immobility, etc) and open design presents an opportunity for those excluded to participate in the design process, such as those people with Cystic Fibrosis. This is a chronic genetic condition, affecting the internal organs and having a very great impact on a person's quality of life; as one example, people who have Cystic Fibrosis are strongly discouraged from meeting together.

Open design by its nature is a collaborative activity, and the work described here aims to prototype a wholly virtual meeting of people, and empower them to conceive and develop their own products based on their own lived experience of Cystic Fibrosis. The project involves the development of a community of people with Cystic Fibrosis, supported through tools and online

workshops with a designer, within an Action Research methodology. It is expected that open design has a positive contribution to make in this field, despite the very real questions surrounding its implementation; and the transition of the designer's role from production of artefacts to facilitating and nurturing design activity is explored in this work.

KEYWORDS: open design, health, medical products

Introduction

There are both moral and pragmatic reasons for including people in the design process (Carroll & Rosson, 2007), moral in the sense that those who depend on the efficacy of a product for their quality of life should have a say in it's development, and pragmatic in the sense that a device that takes this lived experience into account has a greater chance of succeeding[1]. This might be taken as self-evident for the medical product design discipline; however, this is not the case. Elite medical product design consultancies do employ sophisticated ethnographic analysis of populations to ensure that the user is consulted in the design process (Wilcox, 2011), but this falls short of the 'genuine participation' outlined by Kensing & Blomberg (1998) because of the lack of access to information, resources and power to influence decisions. Shah (et, al. 2009) describes a framework for including people in the design of medical products, but crucially the methods outlined rely primarily on consultation (Arnstein, 1969) of the people who have to live with the medical products that are developed, rather than methods that empower the participants to make changes, as expressly stated as necessary by Robertson & Simonsen (2012).

Participation, and exclusion

Participatory design is built on the principle that a person has a right to be involved in the development of an artefact that will affect their being. As such, participatory design as a methodology has been applied by a wide variety of interdisciplinary practitioners in many different contexts. Collaborative Design (Co Design) refers to the act of designers and non-designers (other stakeholders) working together in the design development process (Sanders and Stappers, 2008). Co Design has been applied to the design and development of medical devices (Chamberlain & Roddis 2005, Swann 2011) with demonstrable success via awards conferred, and user review. As participation in the design of medical devices is a goal worth pursuing, any barrier

[1] For a 'free at the point of delivery' system such as the NHS, the success criteria here might be the compliance of a person with their self-management regimen.

to such activity should be highlighted and mitigated. However, Including people in the design process is difficult, taking time and energy from the participants and careful planning to make the work applicable for industrial practice (Pedersen & Buur, 2000).

Some medical conditions have associated complications that provide barriers to inclusion in traditional participatory design activity. Some conditions are very rare, meaning large distances separate those afflicted by them. Taboo, or embarrassing effects of some medical conditions might mean that the lived experience of people living with them is not readily shared, and there are also examples of conditions that render a person immunocompromised, and therefore unable to meet others with a similar condition for fear of cross-infection.

Cystic Fibrosis

Cystic Fibrosis is one such chronic, genetic condition. The disease results in thick mucus impairing the function of internal organs, and also increasing the occurrence of infection within them. Chiefly affected are the lungs and digestive system, although the pancreas's function can also be impaired, resulting in Cystic Fibrosis-induced diabetes. The effect of this attrition on the internal organs of a person with Cystic Fibrosis has a massive impact on their quality of life, with regular spells in hospital, an intensive daily management regimen and increased risk of a required lung transplant. Included in this regimen are numerous devices for the administration of vaporised antibiotics (to prevent Lung infections), steroids, and enzymes taken with meals to better aid the absorption of nutrients. Alongside this, physiotherapy is also used to break down the mucus, and aid its expulsion. People with Cystic Fibrosis are strongly advised to not meet with one another, and as such are isolated even in clinics; this increases anxiety (Cystic Fibrosis Trust, 2004), but is necessary to protect against B. cepacia bacterial infection (Orenstein, 2003).

The range of products required for administering drugs, providing physiotherapy support, and oxygen (in certain cases) is broad. As such, the scope for redesign is also broad.

This paper reports on some initial findings in a research project that seeks to test the efficacy of open design in the development of medical products, specifically those used by people who have Cystic Fibrosis.

Open design

The foundations for the methodology we call open design are not new. As Atkinson (2011) remarks they represent a move 'back to the future'; Indeed in the writings of the economist E.F. Schumacher (1976) and the socio-political commentator Ivan Illich (1975), both laid down a call to move towards more localised and fulfilling methods of production. For instance, Schumacher (1976) writes that in order to facilitate this, technology should be developed that is 'cheap enough to be deployed to virtually everyone, suitable for small-scale application, and compatible with man's need for creativity.' Similarly, Illich (1975) states that any tools (or technologies) must be compatible with 'fully satisfying, imaginative and independent work'. Open design itself embodies these ideals, with the use of convivial tools and spaces including domestic, open-source 3D printing and Fab Labs (Dexter & Jackson, 2012).

Definition

The Open Knowledge foundation recently published their 'version 1.1' open definition (OKF, 2012), which represents a collaborative effort to define the requirements for an open project to adhere to. More specific to open design, there are individual definitions, and classifications of different requirements for applying the label open design to a particular methodology. For instance, Atkinson (2011) describes open design as:

> *"The internet-enabled collaborative creation of artefacts by a dispersed group of otherwise unrelated individuals."*

This process can be summarised in the following diagram, which highlights the different actors in the process, and the places in which the activities take place:

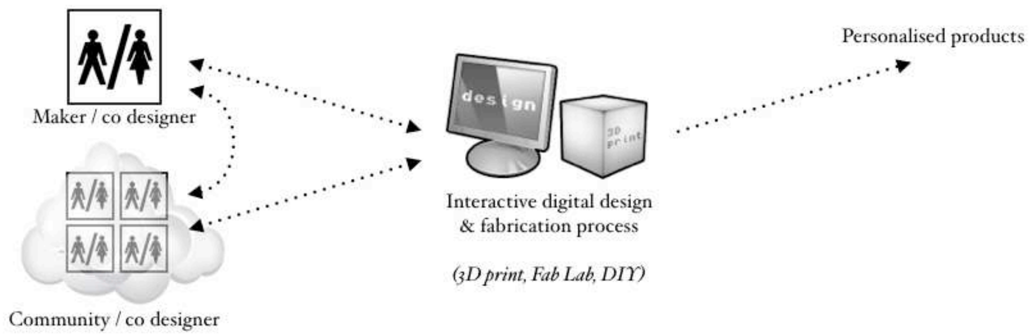

Figure 1. Open design diagram (adapted from Orchestral Manoeuvres In Design, Atkinson, 2011)

The person wishing to engage in the design of a product (here described as the Maker, since open design is concerned with the production of physical artefacts) may begin from scratch, or take as their starting point a design that has already been created by another person and uploaded to a shared community space. Once in this community, the designer has the opportunity to set boundaries on the types of activities that can be carried out; for instance, by applying a Creative Commons[2] licence another maker can easily choose from a range of conditions relating to the production and dissemination of that artefact.

[2] A Creative Commons (CC) licence works in addition to the legal copyright that a creation is entitled to. CC licences allow a person to add stipulations allowing for an idea to be shared by other people, whilst still retaining some degree of ownership of this original idea. For instance, the most permissive of licences allows a person to freely distribute the idea, make derivatives, and even to use the idea (or derivative thereof) for financial gain, as long as the original idea and creator are attributed. The most restrictive allows only for the works to be shared in their original form, with full attribution of the original author. Originally (and mainly) used for digital works such as pictures and music, the CC licences are increasingly being applied to CAD data to aid in the dissemination of ideas for domestic or distributed manufacture.

Open design relies upon sharing, which puts the movement at odds with traditional models of idea-ownership (or, intellectual property). As Neelie Kroes (2011) argues, traditionally copyright was intended to recognise and protect artist's work, but too often the same system is used to punish and withhold information.

Kadushin (2010) outlines in his manifesto 2 basic preconditions for open design, and the sharing of the blueprints that enable it:

- An Open Design is CAD information published online under a Creative Commons license to be downloaded, produced, copied and modified.
- An Open Design product is produced directly from file by CNC machines and without special tooling.

  These preconditions infer that all technically conforming open designs and their derivatives are continuously available for production, in any number, with no tooling investment, anywhere and by anyone.

As Katz (2011) highlights, at it's core these preconditions and way of working give the user four freedoms; "The freedom to use the design, including making items based on it, for any purpose... The freedom to study how the design works, and change it to make it do what you wish."

Once the idea has been shared, or copied from an existing one in the community, the maker can then produce that idea with the blueprints available in the community. Fabrication can be facilitated in the community via a Fab Lab, Hackerspace, or some such, or if the maker possesses the right equipment (such as a 3D printer, or CNC router) then these ideas might be produced at home.

This open way of working empowers the community members who participate by giving them the chance to not simply be consulted on an existing design, but challenge the direction of the process, or start an entirely new line of enquiry; both of these opportunities exist in a 'traditional' collaborative design project, but as highlighted in this paper there are still those who find themselves excluded. Open design therefore represents an opportunity to genuinely empower those people excluded from the participatory design process.

Open design for medical products

This open design process levels the playing field for all participants in the process, making every contributor's efforts valid; even ideas that are flawed add to the dialogue because these ideas are presented with all supporting information and documentation, meaning that these failures can be learnt from. This approach is emancipatory, allowing a person to not only be consulted, but also have the power to make a change in the process, even as far as suggesting new directions for exploration. Since open design allows for genuine participation, it also allows individuals to flourish by learning new skills and engaging in the process of conception and development of the products that they want and need to maintain their quality of life.

Open design, as distinct from Open Innovation

Although sharing similar names, there are important distinctions between the two approaches. There is a recognised need for open innovation within medical product development (Barrett, 2010) with one example being Coloplast's 'Innovation By You' initiative. The company has built a community of renal care patients, who share best practice of using Coloplast devices, support one another and contribute to competitions run by Coloplast for new product ideas. Some members are also invited to a 'VIP' area, where they can work with employees on new products with the work remaining tightly controlled by Coloplast. In this instance, the community that Coloplast has cultivated exists to support itself in the daily life with Ostomy care (hints and tips to get the most out of certain products, support forums, etc). This approach is consistent with Chesborough & Crowther's (2006) definition, but it is not open design in the sense of Atkinson (2011) because Coloplast retain all control over new product designs and do not make the plans or rights to replicate or modify the products available.

Even within fields where closed R&D policies are standard practice (indeed, traditionally considered the only way to practice) there is a move to share information and designs. The pharmaceutical industry, facing mounting development costs (approximately $1.3 billion USD per drug) and lower revenue from patented products is beginning to explore the potential of open-source approaches (Mehen 2011).

Coordinating and Stimulating Open Design

An important aspect of open design is the community of practitioners, and the space in which they meet; or, the vehicle by which ideas are disseminated. Leadbeater (2009) discusses what spaces are most apt for the sharing of ideas. This involves more than the mechanics of uploading documents and data, the whole process should be one that is as transparent as possible.

The Design consultancy IDEO is a notable example of a business that uses open design-openIDEO[3] originally recruited a community from Facebook; Tom Hulme (2011) acknowledging that in order to effectively build a community then one must recruit from where people already congregate. Other authors have written about how difficult building a community can be, and from our previous experience trying to create a community from scratch, it is not enough to assume that 'if you build it, they will come'. IDEO leveraged their reputation to attract interested parties from a general community through Facebook, then created a bespoke space where people can upload ideas, and then build on them. User's ideas have creative commons licenses attributed to them, for dissemination and attribution. IDEO's model for open design is very orchestrated, with IDEO posing challenges with sponsors. The stages of the process are timed by IDEO, with individual participants receiving a 'badge' showing their levels of participation in different aspects of the design process.

[3] http://www.openideo.com/

This contrasts with another community of people who design and share with one another. Thingiverse.com is a community that was created by Makerbot, with little orchestration and direction about the artefacts that are designed. Makerbot will occasionally have sponsored efforts where community members are invited to produce certain artefacts for a theme, but the vast majority of direction comes from the individual members. These same members propose, design and produce their own creations, or derivatives of other people's work.

Both of these examples deal with the complexity of transparently facilitating the dissemination of ideas, but both are organised in different ways. openIDEO uses an orchestral model, being centralized & defined; and Thingiverse.com having more of a creative bazaar approach (Nambisan & Sawhney, 2010).

The role of an industrial designer is changing, and just as Industrial designers are no longer concerned simply with the form, function and production of artefacts but also the services they fit into (Valtonen, 2007), in open design the designer's role is more that of conductor (Atkinson, 2011), bringing together a group of people to and orchestrating the creation of a beautiful piece. Similarly, a designer within open design becomes a designer of toolkits and environments, allowing others to design for themselves, or collaborate with others (Press, 2011, De Mul, 2011).

Methods

The aim of our research is to understand how open design might be integrated into the development of medical projects. Since there is no precedent for using open design for medical product development, there is no opportunity to study prior art. Our research therefore uses case studies to test the hypotheses related to open design. This research is based on practice, and as such, case studies are a natural way to test these theories, since they can be shown to mirror the design process (Breslin, et al 2008). Action research is the fundamental methodology guiding our activity. Archer (1995) states that Action Research is sometimes the best way to test certain complex propositions. Action Research is a valid way of conducting a design case study, since it is seen as a sufficiently rigorous methodology for creating knowledge in fields traditionally favouring positivist methodologies (Checkland & Holwell, 2007, Avison et al, 1999)- medical product design being a good example. In order to make the implementation of Action Research sound, the record keeping must be comprehensive, and also transparent. All preconceptions and bias must be recorded, and carefully weighed against the findings.

An issue with using Action Research is the specificity of the findings, due to the specific nature of the testing (Bødker et al, 2007), but as Archer (1995) and Checkland & Holwell (1998), point out, this specificity is not necessarily a barrier to the creation of new knowledge; indeed with no prior art to examine, the artefacts created by this open design method will embody knowledge created through the group's work- recorded as part of the Action Research process.

The primary assumption is that this process of using open design will be more inclusive, participatory, and be beneficial to a range of stakeholders in the medical product design field, including producers of medical products and the people that have to use them. Manufacturers of these products stand to benefit from the lived experience as a source for constant research and development, and the people who must use the products stand to benefit from products that better fit within their lives.

It is not the assumption of this research that open design will replace traditional medical product design; rather that it will form part of a hybrid model of open and closed development processes, as mentioned by Leadbeater (2009) who postulates such systems.

Case Study 1

In order to test the assumptions above, we are seeking to build a community of people with whom to design medical products. The case study was started in March 2012, wherein it entered an 'Alpha' phase where all of the necessary components were assembled, and the space itself was created. The project then recruited the first community member via a personal contact with the wider research team, opening the 'Beta' testing phase where initial content was created to populate the space. During this Beta phase, a community 'champion' was identified and recruited, through which more people have been introduced to the project. This champion, and the alpha tester (along with the researcher) further worked on the site, welcome pack, and ideas before the opening call was posted in June 2012. Since this time, two extra community members have joined.

Drawing on recommendations in the open design literature, a suitable social network space has been created online. This space allows for the introduction and dissemination of designs, and also a place for people to tell stories about their own lived experience by posting YouTube videos and images. To give the case study a clear identity, and to make references to the space less cumbersome in correspondence, the case study has been branded as AIR. The name is intended to mirror the diffuse and dynamic nature of the process of open design. It is an assumption of the researchers that quality production values will inspire the community members to contribute, and own the process. An example of the branding is shown below, with the logo and colours used throughout (see over).

Figure 2 – Logo and colours for the fist case study

A website[4] was also created to provide information about the project to potential participants, as well as acting as a way to spread information about the project.

In order to allow the community members to develop their ideas, and facilitate the design process each member is sent a welcome pack that contains stationary traditionally associated with design activity. This welcome pack is branded a 'design toolkit', and is modelled on the ideas of Toolkits for Innovation and Design (Franke & Piller 2004), which aim to allow people to 'un-stick' the ideas they have, and communicate them to others. An example of the welcome pack is shown below:

Figure 3 – Example of the welcome packs distributed to community members

Ideally, as well as this welcome pack we would send out a domestic 3D printer, in order to enable the participants to produce their own prototypes, iterating as they go. However, due to cost this is not possible; so a single MakerBot Replicator has been purchased to print any items that come

[4] See the information website at the following URL: http://airdesignspace.businesscatalyst.com/index.html

from the research. The decision to use a MakerBot printer instead in addition to the advanced 3D printing technologies available at the university is deliberate, since this represents the current state-of-the-art for domestic fabrication. As such, the prototypes that are produced in the space will be constructed at the University, using the fabrication facilities, and then shipped out to the participants. Due to the low ratio to Fab Lab / public ratio, this contingency plan means that the participants have at least some agency in the realisation of their ideas. Provision has been made to help participants acquire materials to help them prototype their ideas themselves, if they so wish (through reimbursement via the University).

Recruitment for this case study has been conducted extra to the National Health Service (NHS), with invitations to participate posted through Public and Patient Involvement (PPI) websites, blog posts, and emails to community representatives of large Cystic Fibrosis communities. This research is ongoing, but the most successful recruitment techniques have involved actively developing a relationship with a 'champion' for the project (a person we found by emailing a large Cystic Fibrosis social network), and posting calls on a Tumblr[5] blog. Currently, the community has four active members, with two prototypes produced. The latest member was recruited by another member of the community, without involvement from the researcher, suggesting that the community itself is gaining some momentum. Two of the members reside in the United States of America, and two live in the United Kingdom. The call to participate is open to anyone over the age of 18 who either lives with Cystic Fibrosis, or lives with someone who has the disease.

Design work

Inside the web space, the discussions and ideas are posted to a 'Design Forum', which allows for rich information to be posted. This can include, images, video, links and rich text. Individual topics cover the different ideas, allowing for clear definition of an individual idea. Crucially, this also highlights the original author of the idea, giving clear attribution. Shown over is a screen shot of the design forum.

[5] http://www.tumblr.com is a successful social blogging platform

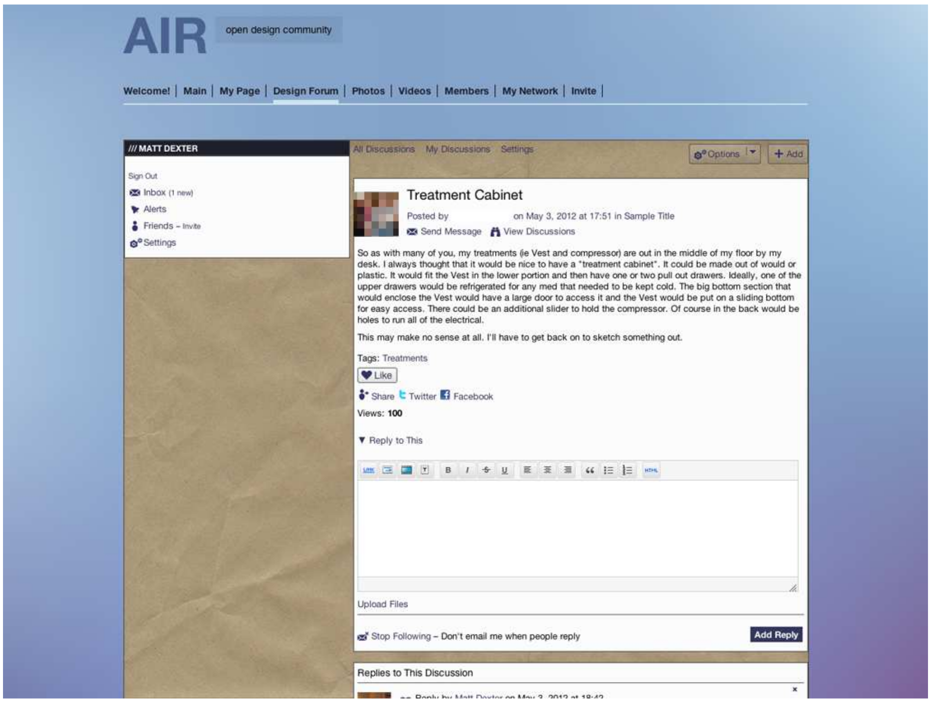

Figure 4 – The 'Design Forum' within the AIR website

Prototypes

So far, there are two prototypes that have been proposed and modelled in initial versions. The first prototype focuses on the storage of drugs that must be administered throughout the day. The initial suggestion was for a bag or organisation system for men with Cystic Fibrosis, since the suggestion from a community member was that women with the disease have the opportunity to store their medication in their handbag, or equivalent. The discussion progressed through the forum on the website and eventually the idea that a pocket liner would perhaps suffice. This 'pocket pocket' was prototyped at the university, and posted to the community member who suggested the idea for evaluation. The prototype as it currently stands is shown over.

Figure 5 – ‘Pocket Pocket’ drug storage prototype

The second prototype originated from a different community member, and concerned the use of physiotherapy vest treatment. This involves the use of an air compressor, which inflates a vest causing it to tighten around the user’s chest. The air supply is then oscillated to produce the same effect as traditional physiotherapy to remove the mucus from the lungs. This treatment is effective as part of the daily self management of Cystic Fibrosis, however the product makes a big impact on the user’s quality of life as there is no solution provided for storage of the compressor, or it’s components.

The other community member that uses a similar product acknowledged this problem, and the suggestion was put forward to design an insert for IKEA furniture rather than a bespoke piece. As such, the community members (the researcher included) set about providing measurements and requirements that were needed for the layout of such a product. The result of the process is shown over.

Figure 6 – The 'Treatment Cabinet' prototype

There were other aspects of this prototype that are still in development. One of the community members suggested that a refrigerated portion of the device would greatly enhance the use, and as such two of the community members (one being the researcher) have continued development specifically on this aspect. This initial insert was shipped to the community member who had the original idea, so that the user could provide an evaluation. The plans for the prototypes are in the web space, making them available to be viewed, produced and modified.

Further work

The process of recruitment has been slow, and difficult. However, with a small but committed community of people (that we expect to grow with fresh expressions of interest in participation) the work is progressing at a steady pace. However, the conversations in the web space are difficult to manage (due to the technical limitations of the forum format), and as such a more structured 'future workshop' will be trialled in the community space along the lines of Reyes & Finken's (2012) work running workshops within Facebook. The tools available are similar, however AIR as a community space allows for a more focussed participation (via the forums) rather than a Facebook 'Timeline'.

Observations and Initial Results

The case study described here is ongoing, and as such these results are preliminary. However, they appear to show an interesting trend; that these prototypes do not challenge the fundamental nature of the interventions required by the community members to maintain their quality of life;

rather that the products described here make these existing products more appropriate to themselves and their lived situation.

This appears to match the assumptions about the role open design might have in the development process for medical products. However, since there are more activities planned for the web space, and more participants having expressed interest in joining, then this assumption has the opportunity for further testing.

The website itself has proven unwieldy in the aggregation of large amounts of data. For instance, the design forum post about the Treatment Cabinet prototype is difficult to read in a chronological order, as the posts are nested; meaning that a reply to a particular post will appear above older posts in the list. This makes the development process difficult to follow, and means that several conversations can take place simultaneously.

Current research being conducted at Sheffield Hallam University aims to develop tools for distributed design workshops, where a digital analogy for the traditional participatory design workshop tools of post-it notes and flip-charts are replicated in a digital way. It is anticipated that the adoption and testing of these tools with this community will aid the conception and development of these concepts.

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