Health products; designed with, not for, end users

DEXTER, Matt, ATKINSON, Paul <http://orcid.org/0000-0002-6633-7242> and DEARDEN, Andrew <http://orcid.org/0000-0002-5706-5978>

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Matt Dexter

PhD candidate, Sheffield Hallam University
matt.dexter@shu.ac.uk *(corresponding author)*
0114 225 6745

Paul Atkinson

Professor of Design, Sheffield Hallam University
p.atkinson@shu.ac.uk
0114 225 6208

Andy Dearden

Professor of Interactive Systems Design, Sheffield Hallam University.
a.m.dearden@shu.ac.uk
0114 225 6878

Abstract

This paper describes research in progress that aims to explore the role that open design could play in the development of medical products. Including people in the development process of medical products has been shown to have benefits to both producers and users but is not universally applied. There are multiple factors from a producer's point of view as to why a collaborative development process is not used, but similarly there are some medical conditions that preclude a person's involvement in collaborative group work. For example, people who have the chronic condition Cystic Fibrosis are excluded from traditional collaborative design sessions due to susceptibility to certain communicable diseases.

Open design offers the opportunity for people normally excluded in collaborative design processes to not only be included, but also shape the direction of the enquiry. Through the use of social media, and other collaborative internet-enabled tools the dissemination and development of ideas can occur. This goes beyond the fundamental moral and pragmatic arguments for collaborative working, since the knowledge and experience of the people participating is harnessed and available to all. This process therefore bears the hallmarks of a truly emancipatory technique, compatible with the notion of human flourishing and that the concept of a person's 'health' extends beyond a mere absence of illness.

The research is based around a series of practical case studies within an Action Research framework, the first of which is outlined here, where artefacts will be produced using open design; drawing upon established methods using prototypes as research and trialing the combination of physical tools (e.g. 3D printing) and virtual meeting spaces to facilitate the design activity.

Introduction

Early in 2007 an article in the Guardian newspaper appeared- 'Should Apple start manufacturing insulin pumps?' (Bevan, 2007) which expressly links the design practices of Apple with their success, and asks why the same emphasis on design is seemingly absent from the products that people with a chronic condition depend upon. This paper describes a radical approach to this problem by exploring the potential of open design.

In order to include people in the design process, and recognising that collaborative methods of designing are emancipatory and have been used successfully in the past, the aim is to apply these collaborative techniques in circumstances where physical collaboration is not possible. This may be due to a person's condition, or perhaps geographic location. The work will initially begin with people who have cystic fibrosis, using open-source design (open design), since this is a new approach in medical product design, with no set precedent.

Background

People in Medical Product Development

Two imperatives are often cited for including users in design- the moral and the pragmatic (Carroll & Rosson, 2007). Moral, in the sense that those who will be directly affected by the design of a product should have a hand in how that product comes about, and Pragmatic, in the sense that there is a greater chance of the product succeeding if those intended to use the outcome are included. This process can be shown to produce quality work, and can also have an emancipatory effect for those involved (Noble & Robinson, 2000).

There is a documented need to include the users perspectives' in the design process; Shah, et al (2009) note their views are 'particularly important'. However, a number of difficulties are cited in including users during the development process in a traditional medical product company, including: retaining participants, and the costs associated with activities (Shah, et al 2007); and cultural attitudes of the organisation (Kauppinen, et al 2002). 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). Another issue is the pervasive tendency to view users of medical products as a homogeneous group, rather than recognizing the diverse perspectives of distinct individuals (Shah et al 2009).

On the other hand, certain élite medical product design consultancies certainly do include users via rigorous ethnographic analysis (Wilcox, 2011), and the success derived from this inclusion is apparent- new product ideas, reductions in development costs, improvements in usability, safety & the identification of problems early in the development process (Shah et al 2009). Taking this idea further, (beyond consultation and focus

group participation) collaborative design techniques have been used successfully in projects designing novel medical products (Swann, 2011, Chamberlain & Roddis, 2005).

However, some people may be unable or unwilling to participate in traditional face-to-face collaborative design projects. For example, people with Cystic Fibrosis cannot meet together because of the potential danger of transmitting the *B. cepacia* bacterial infection (Orenstein, 2003). Other groups of people may feel inhibited in face-to-face design activities because of the very personal nature of their medical conditions. Still others may be separated by large physical distances from others who have the same rare condition. Open design offers the potential to broaden the range of people who can be involved in medical product design, and to open up new ways of participating.

Open design enables people to participate in this process on a level playing field; they are empowered to influence the development of these products. All ideas are publically available, in the same way that the company's ideas area available. This approach frees them from the hierarchy that exists with user consultation approaches; this is emancipatory. In so doing, this allows people to flourish by learning new skills and engaging in the process of designing the artefacts that they want and need.

Open Design

Open Design relies upon the sharing of ideas within a community of people engaged in the design process, who meet within a space – usually online, although certain physical spaces (Fab Labs and Hackerspaces) have developed where ideas and designs are generated and then disseminated (via the internet). According to Atkinson (2011) open design is:

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

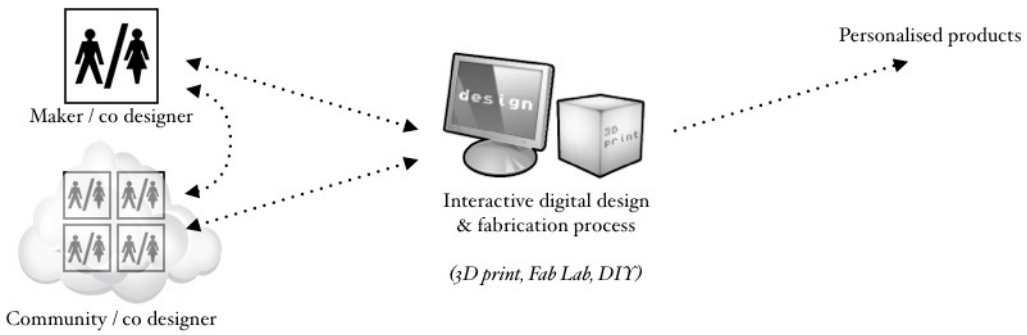

Figure 1 – Open design diagram (adapted from Orchestral Manoeuvres In Design, Atkinson, 2011)

The person (here described as a Maker) designs from scratch, or takes another person's design and alters it. The Maker can then either engage in a co-design activity with the wider community or proceed directly to fabrication, using 3D printing in their own workshop, or they may use shared facilities in a community space such as a Fab Lab (Fabrication Laboratory) or Hackerspace. This model allows for a person to either initiate a design, or build from another idea within the community. The community is formed around a core of interested and motivated people, who cultivate activity and sometimes provide direction for the development of some particular ideas (Leadbeater, 2009, Surowiecki, 2004).

Traditionally, the development of products by amateurs has proved difficult, with a high barrier to entry (requiring expensive machinery & software; and/or professional qualifications). However, domestic low cost 3D printing has come a long way in a few years, allowing people to produce detailed, high quality prototypes, and iterate quickly to learn from their failures (as professional designers do). For example, Adrian Bowyer invented the RepRap 3D printer in 2004 (Bowyer, 2004) as a way of creating a low cost 3D printer that could copy itself, and allow people to produce high-resolution parts and objects for themselves. 3D printing is an important enabling technology for open design. It is only recently that there has been an explosion of open-source, inexpensive 3D printers available. The ability to create a digital drawing of an object, and inexpensively print it out lowers the barrier to entry for designing one's own products. As an example, an open-source, consumer 3D printer is approximately 10x cheaper than an industrial version1. Similarly, the Computer Aided Design (CAD) software required for producing a drawing that can be printed has plummeted, to the extent now that many pieces of software are free to download and use.

Open Design versus Open Innovation

Medical product manufacturers have recognised the need for strategies to involve users in designing future products (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. This example demonstrates that the benefits of a community of users stretch beyond simply product innovation – to product and personal support. However, whilst Coloplast's strategy can be described as 'Open Innovation' as described by Chesborough & Crowther (2006), it does not

[1] The desktop variant of the Objet 24 (*http://www.objet.com/3D-Printer/Objet_Desktop_Family/*) costs approx £18,000. The MakerBot Replicator currently retails for approx £1800, 10x cheaper than the Objet 24. The new Printr 3D printer retails for approx £320, over 56x cheaper. Of course, the Objet printer has a range of materials that it will print, flexible and optical grade transparent for instance, whilst also being more accurate. However, for many home users, the excellent accuracy offered by the MakerBot and Printr are more than adequate- while the prices reflect just how affordable this technology has become.

constitute ‘Open Design’ in the sense of Atkinson (2011) because Coloplast retain control over any new product designs and do not share the right to further replicate and modify the designs.

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. With the development of open source software, there have also been a myriad of different licenses created that allow the dissemination of ideas, ensuring that the original author is credited, and derivatives have no further restrictions placed upon them. 10 years ago, the Creative Commons (CC) license was created, to provide an easy way of licensing work for dissemination online. These licenses are used by some of the largest open design communities operating today.

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[2] 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.

[2] 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 to 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.

As it is an important condition for good Action Research that assumptions be listed beforehand, these can be summarised here:

It is assumed that open design will allow for a more inclusive, participatory, design process that will have benefits for a range of stakeholders in the production of medical products. Manufacturers stand to benefit from the designs produced by those with lived experiences as a source of research and development, and the users of those medical products stand to benefit from products that better fit their lives.

It is not the view of this research that open design will replace the traditional model of medical product design in it's entirety, but that a hybrid model combining open and closed development is most likely. This is a view shared with Leadbeater (2009), who describes such a system.

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. Drawing on recommendations in the open design literature, a suitable social network space has been created online.. 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:

Figure 2 – Logo and colours for the fist case study

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

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[3] blog. Currently, the community has 4 active members, with 2 prototypes produced. The latest member of the community was recruited by another member of the community, without involvement from the researcher, suggesting that the community itself is gaining some momentum.

Conclusion

Open design offers an opportunity to include more users of medical products in their design, and to also allow for innovation to come from those same users. There are potentially substantial benefits to this process; promising innovations and products that are more fully suited to those who have to use them, and in creating a community of users who can support and aid the development of new products. However, a fully open-source development process may appear daunting to medical product developers, with questions remaining about ownership of ideas, the commercial implications for manufacturers, and the how such a process might be related to 'in-house' design activities. It is the purpose of this research here to explore some of these questions, by putting these ideas into practice, and reflecting on the outcomes as they appear.

[3] www.tumblr.com is a successful social blogging platform

References

Atkinson, P (2011). Orchestral Manoeuvres In Design. In: Van Abel, B (et al), *Open Design Now*. Amsterdam, BIS Publishers.

Archer, B (1995). The Nature of Research. *Co-design, interdisciplinary journal of design*. 6-13

Avison, D, Lau, F, Myers, M, Nielsen, P A (1999). Action research. Communications of the ACM. 42 (1), 94-97ARCHER, B (1995). The Nature of Research. Co-design, interdisciplinary journal of design. 6-13

Barrett, P (2010). The Race for Open Innovation [online]. Last accessed 7th January 2012 at: http://www.emdt.co.uk/article/race-for-open-innovation

Bevan, Kate (2007). Should Apple start manufacturing insulin pumps? [online]. *The Guardian*, 12th April. Last accessed 19th December 2011 at: http://www.guardian.co.uk/technology/2007/apr/12/guardianweeklytechnologysection.gadgets?INTCMP=SRCH

Bowyer, A (2004). Wealth Without Money - The background to the Bath Replicating Rapid Prototyper Project [online]. Last accessed 20th December 2011 at: http://reprap.org/wiki/BackgroundPage

Breslin, M & Buchanan, R (2008). On the Case Study Method of Research and Teaching in Design. *Design Issues*. 24 (1), 36-40

Carroll, J. M., & Rosson, M. B. (2007). Participatory design in community informatics. *Design Studies*, 28(3), 243-261

Chamberlain, P & Roddis, J (2005). Regenerate: a case study of a collaborative design research led new product development. In: *Joining forces: Design research, industries and a new interface for competiveness*, University of Art and Design, Helsinki, 22-24 September 2005.

Checkland, Peter & Holwell, Sue (2007) Action Research: Its Nature and Validity. *Integrated Series in Information Systems*. 13 (1) 3-17

Chesbrough, H & Crowther, K (2006). Beyond high tech: early adopters of open innovation in other industries. [online]. *R and D Management*, **36** (3), 229-236. Article from Wiley, last accessed 1st August 2012 at: http://doi.wiley.com/10.1111/j.1467-9310.2006.00428.x

De Mul, J (2011). Redesigning Design. In: VAN ABEL, B, EVERS, L, KLAASSEN, R, & TROXLER, P (eds) *Open Design Now*. Amsterdam, BIS, 34-39.

Franke, N & Piller, F (2004). Value Creation by Toolkits for User Innovation and Design: The Case of the Watch Market. [online]. *Journal of Product Innovation Management*. 21 (6), 401-415

Hulme, T (2011) openIDEO. [presentation]. Held on the 2nd March. *Intersections 2011* Creative Business Summit, Eden Project, Cornwall

Kauppinen, Marjo et al. (2002). Introducing requirements engineering: How to make a cultural change happen in practice. Requirements Engineering, 2002. *Proceedings. IEEE Joint International Conference*. 43-51

Kroes, N (2011). Is copyright working? *EU Digital Agenda Commissioner Blog*. [online]. Posted November 21st at: http://blogs.ec.europa.eu/neelie-kroes/is-copyright-working/

Leadbeater, C (2009). *We-Think: Mass innovation, not mass production*. London, Profile

Nambisan, S & Sawhney, M (2010). Making the Most of the Global Brain for Innovation. *International Commerce Review*. 8(2) 128-135

Noble, A & Robinson, C (2000). For The Love Of The People: Participatory Design In A Community Context. In: Stephen A. R. Scrivener (et al), *Collaborative Design*. London, Springer-Verlag, 81

Mehen, L (2011). Drug companies try sharing. Open Source.com. [online]. Posted 21st October. Last accessed 20th December 2011 at: http://opensource.com/health/11/10/drug-companies-try-sharing

Orenstein, D (2003). *Cystic Fibrosis: A Guide for Patient and Family*. Philadelphia, Lippincott Williams & Wilkins

Pedersen, J & Buur, J (2000). Games and Movies: Towards Innovative Co-design with Users. In: Stephen A. R. Scrivener (et al), *Collaborative Design*. London, Springer-Verlag, 93.

Press, M (2011). Working the Crowd: Crowdsourcing as a Strategy for Co-Design. In: Cooper, R, Junginger, S & Lockwood, T (eds) *The Handbook of Design Management*. New York, Berg, 512-531

Shah, Syed Ghulam Sarwar & Robinson, Ian (2007). Benefits of and barriers to involving users in medical device technology development and evaluation. *International journal of technology assessment in health care*. 23(1), 131-137

Shah, Syed Ghulam Sarwar et al. (2009). Developing medical device technologies from users' perspectives: a theoretical framework for involving users in the development process. *International Journal of Technology Assessment in Health Care*. 25 (4), 514-521

Surowiecki, J (2004). The Wisdom of Crowds: Why the Many Are Smarter Than the Few. London, Abacus

Swann, D (2011) 'NHS at home : a co-design research project to develop a 21st century nursing bag'. In: *Ergonomics and human factors*, 12-14 April 2011, Stoke Rochford, Lincolnshire

Valtonen, A. (2007). *Redefining Industrial Design: Changes In The Design Practice In Finland*, University Of Art And Design Helsinki

Wilcox, Alun (2010). *Medical Product Design: Yesterday, Today and Tomorrow*. [online]. Last accessed 01 December 2011 at: http://www.emdt.co.uk/article/medical-product-design-yesterday-today-and-tomorrow