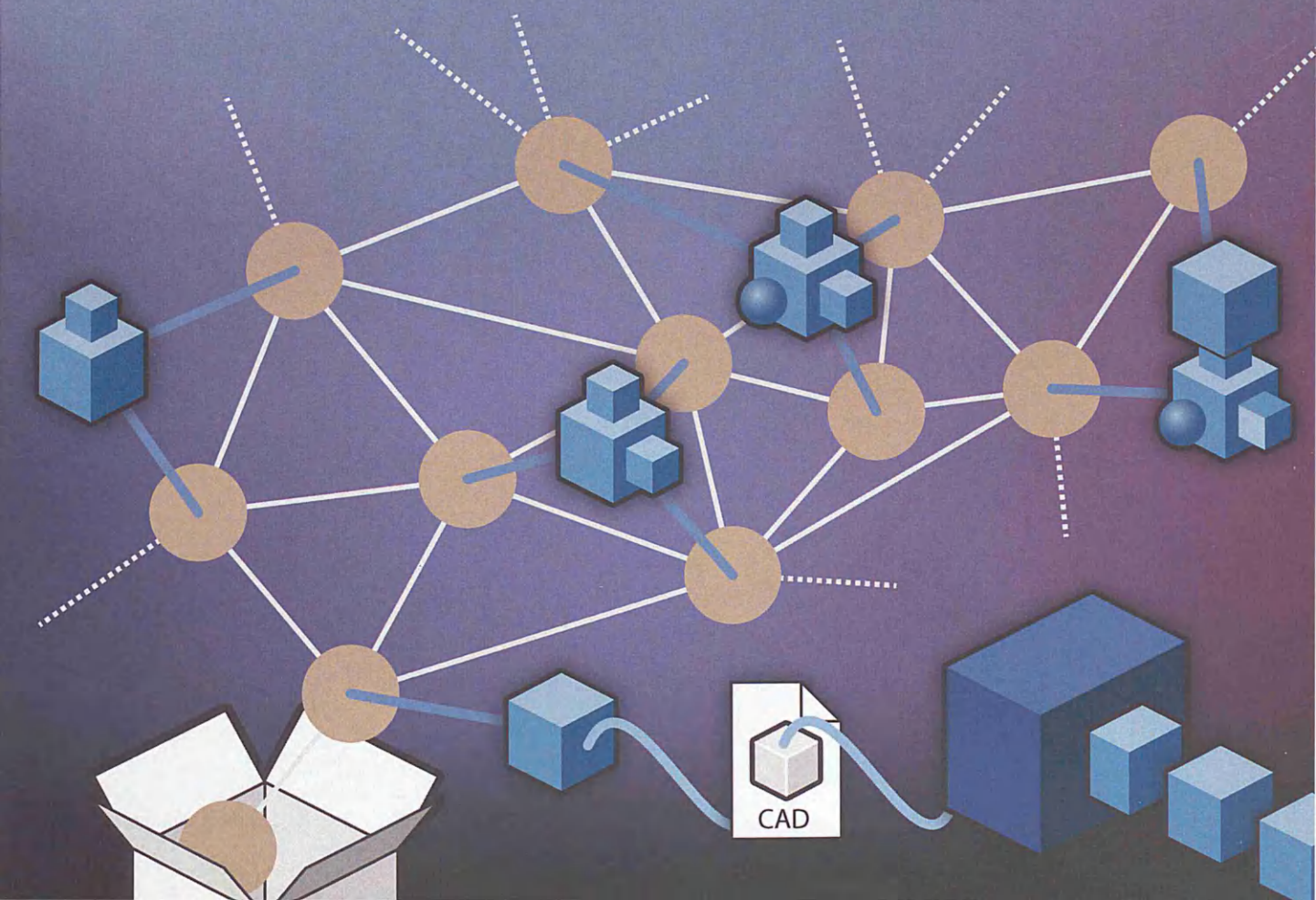
OPEN DESIGN AND MEDICAL PRODUCTS

an Open Medical Products Methodology

Matt Dexter



Open Design and Medical Products

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Abstract

Open Design and Medical Products – an Open Medical Products Methodology

This research details the use of Open Design to enable participation in the conceptualisation, design and development of medical products for those who are excluded by their chronic health condition.

The research was directed according to the Action Research methodology outlined by Checkland & Holwell (1998); Action Research being highlighted by Archer (1995) as a method compatible for practice-led design research.

Open design directed the design practice, which consisted of a long case study spanning 18 months from February 2012, through to July 2013. This case study, dubbed AIR involved the creation of a bespoke online social network, recruitment of people living with cystic fibrosis, and the facilitation of collaborative design work resulting in prototype medical devices based on the lived experience of the participants.

The work involves research into design within health as the context for this research. In order to place design in this wider context, it has been tempting to adopt the mantle *Evidence Based Design* (Evans, 2010) – however in this research the position of design as *phronesis*, in a similar manner to health practice (Montgomery, 2005) is adopted. This allows for an alignment of the work done in both fields, without the problematic associations with an evidence hierarchy (Gaver & Bowers, 2012; Holmes, Murray, Perron, & Rail, 2006).

The contribution to knowledge is an *Open Medical Products Methodology*, consisting of the artefacts supporting the evidence of the methodology's ability to foster genuine participation amongst those who are excluded from traditional participatory design. The artefacts constituting this submission are this thesis, the reflective log kept during the research (Appendix A), the prototypes from the collaborative research (Appendix B), and the online social network that contained the work (AIR[1]).

The *Open Medical Products Methodology* is expected to be of interest primarily to designers of medical products, design management and policymakers- although Open Design as a product methodology has appeal to other sectors and the future work into standardisation, regulation, distributed manufacture and recruitment detailed at the conclusion of this thesis has application broader than the medical field.

[1] http://airdesignspace.ning.com

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The academic and support staff at Sheffield Hallam University have also been key in facilitating the making of prototypes, organising ethics and governance, and even helping to sort the finances.

Of course, a PhD is not just about the research that's conducted by me as author- the guidance and support of my supervisor Prof Andy Dearden and Director of Studies Prof Paul Atkinson has been key to the success of this work.

AIR would not have been the success that it was, were it not for the participation of Holly van Geffen, Amber Richter or Ronnie Sharpe, and all who participated in AIR- I am indebted to all of you for your input and support. Thank you.

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Soli Deo Gloria!

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1. Background

1.1. Introduction

People have a right to be included in the design and development of artefacts that will affect their lives, with this being especially true of artefacts that people rely upon to maintain their quality of life. Products that embody the lived experience of the different stakeholders have the potential to be more commercially successful, and also not abandoned by being unfit for purpose.

Some people are barred from exercising this right to participate, to the detriment of all stakeholders. In the context of designing artefacts for health provision the state of a person's health might be the excluding factor- for instance, those who live with a chronic condition might be affected by being immunocompromised; they might have a condition with taboo side effects or self-management processes; they might have a rare condition, meaning fellows with the lived experience are geographically dispersed; or they might be infirm, and unable to attend participatory design sessions.

1.1.1. Backstory

Towards the end of my undergraduate Product Design degree I became interested in the development of medical products, but with the user in mind. In learning to listen to the person who had to use the product, and recognising that perhaps as a designer I didn't have all the answers, I became increasingly aware of the role the user *had* to play in the design process.

My undergraduate work focussed on the development of a novel Diabetes management tool, and involved discussions and interviews with people who lived with Type 1 diabetes. It also involved personally trying out different equipment (where this was safe to do so) including the fitting of a 1-inch subcutaneous infusion needle[1], worn for 24 hours and taped to my mobile phone- simulating life with an Insulin Pump. Empathy is a requirement for designers; particularly those working in a participatory context (Steen, 2012), and this work was good training in the practicalities that this approach entails.

After my undergraduate degree, I worked in a consultancy and produced some work on a freelance basis. This practical experience was very valuable, since it exposed me to the pressures and minutiae of design practice.

The opportunity to pursue more research into this User-centred approach to design and to explore the different levels to which a person can be involved in the development process came in the form of a Masters qualification here at Sheffield Hallam University. During this,

[1] These needles form the method by which Insulin is administered during Insulin Pump therapy. A needle should be fitted each time the cartridge of Insulin is depleted (typically 2-3 times a week). This involves injecting a long, very sharp needle into the fatty tissue around the stomach, or thighs (typically), and withdrawing the needle to leave a soft silicone hose in the subcutaneous tissue, which if administered correctly does not cause discomfort to the wearer.

I designed new Stroke telerehabilitation[2] equipment, with the direct input of Stroke survivors. This research was fundamentally User-centred and through the use of focus groups the prototypes developed to be much more compatible with the users' needs. However, viewed from Arnstein's (1969) *Ladder of Citizen Participation* this involvement was more consultation than collaboration. Towards the ends of the project, the focus groups became more collaborative, with participants suggesting alterations to the design, and altering the prototypes themselves.

This User-centred design work prompted more research into the role participatory design can have in healthcare, which was undertaken in a Research Associate post for the research group User-centred Healthcare Design (UCHD), within the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South Yorkshire research pilot[3]. This work further developed the sense in which a person can be considered to be a part of the design process, especially when I was seconded to the Lab 4 Living project *Future Bathrooms*. Here, the user voices were difficult to capture because of the private nature of the participant's activities in the bathroom (Chamberlain, Reed, Burton, & Mountain, 2011). Community researchers were recruited and trained by the researchers to access and engage this community, and thus the voices of the participants were included.

There were significant barriers to collaboration, however; some patients are immunocompromised, and therefore have strong restrictions on who they can meet; some conditions are rare, and therefore adequate representation by multiple participants is difficult; some conditions are taboo, and the participants might be strongly against discussing them in a group setting; finally, the difficulties associated with bringing together *any* group of participants still apply- participatory design is *hard*.

The PhD enquiry began as an investigation into the role of collaborative design in the development of personal medical devices. This aim persisted until shortly before the submission of my RF1[4], when it became apparent that a methodology was required to adequately match the challenges of enabling collaboration for these people living with chronic conditions. Through the research interests of my supervisor, Paul Atkinson, I was introduced to the idea of Open Design- and when I saw the distributed nature of the design activity, and the opportunity for deep customisation of the individual products produced the direction of the PhD enquiry changed. This geographic diffusion of the participants in Open Design means that meaningful collaboration in the design process is possible for those who are barred from participation due to their health.

[2] Telerehabilitation equipment monitors the rehabilitation exercises of the user via motion sensors worn about the body. A computer records the information, and displays the result to the user, aiding the rehabilitation process.
[3] CLAHRC is majority funded by the National Institute for Health Research (NIHR).
[4] 'Research Framework part 1' – this document sets out the direction of the PhD study and must be completed within the first 3 months of the PhD. The aims and objectives can change, but s process is intended to shape the early research to ensure the appropriate training and reading happens.

1.1.2. Research Question

How can people who are barred from Participatory Design through living with a chronic condition be included in the design and development of medical products?

1.2. Theory – Open Source Hardware

Open Design is not a new idea, nor does it represent a fundamental shift in the way human beings have produced artefacts, and disseminated knowledge through making. The modern notions of patent protection and intellectual property challenge the paradigm of open source hardware, yet the intersection of modern technologies (the Internet and Distributed Digital Manufacturing[5], for example) means that non-professional users are empowered to hack, repair, and design for themselves.

Such an open paradigm also enables a local model of production and consumption, with raw materials originating from one territory and being consumed in the production of artefacts in the same territory- though perhaps from a design originating from elsewhere. This is 'globally local' production- the next step from Schumacher's (2011) 'Buddhist Economics' (Dexter & Jackson, 2013).

Sources of user-innovation are prized for their insights, and the ability to open up completely new markets worth vast sums of money (von Hippel, 2005). This innovation can be 'invisible', or difficult to adequately capitalise as a business (von Hippel uses the term 'sticky knowledge' residing within Lead Users). Open Design offers the opportunity to make this activity explicit- or to foster it in such a way as to make the design *visible* (to 'unstick' the knowledge). A company or entity can foster this activity to build product evangelists as well as complement their research and development strategy.

Typically, when confronted with a suggestion for an open-source approach to hardware the main objections revolve around the lack of 'security' of the idea. The prevalence of Intellectual Property protection and the pervasive notion that security must be sought before proceeding to development and implementation mean that Open Design (and the open-source hardware it produces) appears at first glance to be anti-business. However, 'if you don't share, someone else will share for you' (Pettis, 2011), and this remains true whether the idea is 'protected' or not. Companies spend large amounts of money and resources to take out 'defensive patents' that protect ideas surrounding the core technology or process of their business. In contrast, a business model favouring a 'first-to-market' approach means that the competition is kept on the reactive, defensive path, and as Nathan Seidle (the CEO of Sparkfun Electronics) points out- this open source approach forces the company to remain innovative.

[5] Distributed Digital Manufacturing is an umbrella term for a collection of computer-controlled manufacturing processes, which can be used to produce a part not necessarily created locally- i.e. this could be a file created in a different location. The manufacturing processes can include, Laser Cutting, 3D Printing (Rapid Prototyping), and CNC Lathing, or machining. This is not an exhaustive list of the processes that could be considered Distributed Digital Manufacturing (section 4.1.1, p 54)

There are other benefits to the open design of hardware. Inviting people to collaborate on a design (even if they simply build their own copy) nurtures a community of people around a product. These people can become product evangelists; be a source of new product innovation; a source of technical support to other members; or even produce artefacts that could form the basis of partnerships with other manufacturers / communities of makers. These niche networks around products, companies, or even chronic conditions would be the engine for this Open development.

In software development, planning as if the code will be open sourced at some point means that the software benefits from the aspects of open source software from the beginning, even if the code remains proprietary (Preston-Werner, 2011). One of the benefits to come from building in this fashion is modular code- the different aspects and features all plug into one another making collaboration easier to manage. Of course, the true benefits of open sourcing a product come from the community that is built. E. S. Raymond (2001b) discusses the different aspects and cultural minutiae that form part of this process in *Homesteading the Noosphere.*

Open Design, and the artefacts that are created in such an open source environment are ripe for this type of development. For instance, *Open Structures* (Lommee, 2014) is a project to develop hardware that conforms to this modular system by basing the interfaces on the Metric system. Open Design can be a powerful tool in the creation of standards for interoperability and compatibility (Raasch, Herstatt, & Balka, 2009).

At this time, the Open Design movement remains nascent within wider design practice- although this is beginning to change. Increasingly, there are initiatives that seek to mimic the successes of open source software for the creation of physical artefacts. This winter (2013) Google are releasing a 'Hardware SDK[6]' for their modular Smartphone project dubbed 'ARA' (Eremenko 2013). Motorola are seeking to do for Smartphone hardware what Android has done for Smartphone software[7]. The maker community goes from strength to strength, with more and more people attending maker fairs, fab labs and Tech Shops. As more people engage with Open Design, the more opportunities there are for developing an increasing range of products in this manner. That is not to say that Open Design should sweep aside all other paradigms of design and development; rather, that a more nuanced view of Open Design (Cruickshank & Atkinson, 2013) is possible akin to Leadbeater (2009).

[6] SDK is an acronym that stands for 'Software Development Kit'. These are tools developed by a software vendor whose product is a platform that other software runs within (E.g. Microsoft Windows, or Apple OSX). These tools help ensure compatibility and a consistent experience for the user.

[7] Android is a Smartphone operating system based on the open-source stalwart, Linux. This port from the desktop version of Linux to one capable of running well on ARM-based phone architecture was begun by Android, Inc.,, and purchased by Google in 2005 to mount a challenge to Apple's iPhone.

1.3. Study

The use of participatory design in the development of medical devices promises to yield a number of benefits for both producer and user. Greater influence on the decision-making process results in genuine participation (Arnstein, 1969; Hess & Pipek, 2012; Kensing & Blomberg, 1998; Luck, 2007)– citizens have the power to change the course / scope of an investigation and as such are not merely consulted or subjected to a token level of participation.

Genuine participation doesn't happen routinely in the medical product development sector, although the benefits of user-inclusion (though not necessarily genuine participation) are noted (Henninger, Elbaum, & Rothermel, 2005; Money et al., 2011; Shah, Robinson, & AlShawi, 2009). Cost, and the difficulties associated with facilitating participation are cited as reasons, but also scepticism about the benefits (Henninger et al., 2005; Karlsson et al., 2011). People have a right to a voice in the development of technology that affects their daily existence (Carroll & Rosson, 2007; Müllert & Jungk, 1987), and as well as this moral duty there is the pragmatic concern; a product that intimately meshes with a person's life will be a more desirable product with a greater chance of success (or adoption) in the marketplace.

This PhD explores a novel method to enable genuine participation in the development of medical products. Open Design is a recent development atop old notions of dissemination for blueprints / ideas. The recent movement, powered by adoption of collaborative web technologies and Distributed Digital Manufacturing is poised to disrupt the traditionally-held notions of 'designer', 'client' and even 'user' (Atkinson, 2011).

Sharing many aspects of open-source software, Open Design (akin with open hardware) allows for the rapid iteration of concepts, with the ability for people to participate remotely (Raasch et al., 2009). This is especially important for involving people with chronic medical conditions, as special restrictions can apply. For example, this research was conducted with people who live with cystic fibrosis, who are immunocompromised and therefore unable to meet together (a requirement for traditional participatory design).

Empowering people to have a voice in the development of medical products is certainly a worthy goal, but there are substantial questions surrounding the implementation of Open Design in this field. Not least the question of liability – who is responsible for a piece of equipment? The original supplier? The community member responsible for the modification or 'hack'?

Difficulties surrounding the standardisation / quality control of open source hardware (including products of Open Design) are not insurmountable (Dexter, Phillips, Atkinson & Baurley 2013). Discussions around the liability of actors in the development of open source medical devices are current. Although, with no test cases on trial at present it is difficult to predict how such a legal case might be ruled.

1.3.1. This Work

This thesis describes a response to the problems of facilitating the participation of people who are immunocompromised in a collaborative design project. There are compromises made in the design of the study, since it imagines a future not yet realised- that is, where access to community workspaces is ubiquitous, and Distributed Digital Manufacturing has become a pervasive technology. This has been managed by the use of the University's workshop facilities, and the use of a domestic 3D printer to produce artefacts that are then posted to the participants for review and comment.

The work revolves around a central case study, where people who live with cystic fibrosis were recruited to an online social media space that was produced to house the collaborative design work. This space was developed with the help of collaborators over a period of months, when it then emerged from a 'beta' state.

The collaborative work was facilitated by a designer (the researcher) in the process, who initiated contact with the participants and then aided in the development and production of the prototypes. This process was a collaboration- the ideas developed out of a dialogue between the community and myself. While it is impossible to separate myself from the products created, the products would be nothing without the participation of the people from the community.

1.4. Summary

The contribution to knowledge from this PhD is the Open Design methodology for the development of medical product prototypes- this is in response to the research question, seeking to include people in a collaborative design project (that is, to foster genuine participation).

The knowledge is embodied in the artefacts that comprise this submission; the thesis (and its Appendices), the case study (AIR), and the physical artefacts resulting from the PhD case study. This piece of research is guided by the principles of Action Research, ensuring rigour in the process but also detailing the *type* of knowledge created. The results from this PhD are not intended to be generalisable in the same vein as research from the natural sciences. Rather, the methodology and submitted artefacts are generative research from a specific time and space- intended to inform design practice.

The context for this research is highlighted in the preceding chapter (*Design in Health* p 11), with the particularities of the research (epistemology, methodology, etc.) in the *Methodology* chapter (p 27), the methodology of the design practice in the *Open Design* chapter (p 46), and the practical work detailed in the *Study* chapter (p 82).

2. Design In Health

This chapter sets out the requirement for a participatory approach to designing and developing health interventions and approaches. This forms the context for the PhD- the dominant research paradigm in a health context (Evidence Based Practice), and the current state of design as conducted by health practitioners (Experience Based CoDesign).

People have a right to be included in the development of artefacts that have an impact on their life (Carroll & Rosson, 2007; Müllert & Jungk, 1987) with this especially true for something as important and personal as health provision. Design is well placed to serve this need, by enabling collaborative approaches to imagining new futures. Design must translate these benefits for the health world to understand. This is a two-way approach, with designers required to understand the dominant paradigms in health provision and tailor their approaches appropriately. This does not mean that a critical approach to the processes found in health cannot be used, but in order to effectively deliver a design-led approach, validation, evaluation and costing metrics must be acknowledged, understood and applied (where appropriate).

2.1. Background

In the United Kingdom, the National Health Service has been the delivery method for healthcare for the general population since the 1940s. At its inception, the health needs centred on the treatment of acute conditions with high transmission rates. The treatment of these conditions was hospital-based, with admission to a ward for care. These contemporary diseases of the 1940s were well served by this model. However, as the population of 21st century Britain ages at an increasing rate, the focus has shifted from acute to chronic care (Cottam & Leadbeater, 2004; Wanless, 2002). Similarly, an increasing number of patients present with multiple, complex conditions that may each require a different management or treatment regime. As the World Health Organisation (WHO, 1948) defines, [good] 'health' is more than the absence of disease or illness; instead it encompasses the mental, physical and spiritual wellbeing of an individual. This notion of health is broader than the narrow definition laid down by the founders of the NHS in the 1940s.

Reforming the provision of 'free at the point of care' healthcare model for the challenges of the 21st century is a difficult task (Cottam & Leadbeater, 2004). Interventions that move beyond the traditional clinic setting are required, engaging people in their own health as active participants- providing people with the tools to be able to take the appropriate actions in the preservation or improvement of their own health. However, these problems are multifaceted, socio-cultural and complex. Often they are Wicked problems (Kunz & Rittel, 1972), with no stopping rule and no single solution available.

Design offers an opportunity to address the complexities of delivering health provision in the 21st century. This is design embedded within the health service, with the healthcare providers, managers, patients (and designers) all engaged in the design process.

Design can be used to tame complex, socio-cultural problems, where the systems and processes within an overall organisation are difficult to untangle without adversely affecting the operation of the whole. Design doesn't require the whole system to be under a microscope, but instead engaging the stakeholders in a collaborative effort to imagine new futures.

Design is not the *only* method used to try and tame Wicked problems, with Systems Engineering used to quantify and optimise; however, optimising the current system might not be optimal for all stakeholders. Instead, the quote often attributed to Henry Ford sums up this idea:

> *"If I had asked people what they wanted, they would have asked for a faster Horse."*

In optimising the current status quo, the opportunity for a genuinely new approach is lost.

2.2. The limits of Design in health?

In 2007, the *Guardian* newspaper published an article entitled *'Should Apple start manufacturing insulin pumps?'* (Bevan, 2007) which linked the success of the iPod product line with the design philosophy of Sir Jonathan Ive; and asked why there appears to be an apparent lack of a similar approach to designing medical products for those who live with diabetes. Tellingly, at the end of the article Sarah Milsom of Diabetes UK is quoted as saying that design already plays a part in the development of devices for people living with diabetes:

> *"You can get insulin pumps for younger patients that sport cartoon characters, while insulin pens, used for injecting the hormone, can be made to look cool"*

This quote belies the presupposition that design is only a force for aesthetic good, and that once the serious engineering or technical work is completed then the designer is simply required to make the product desirable (Crampton-Smith & Tabor, 1996). Indeed, the view that 'form follows function' is a naïve belief (Krippendorff, 2007), particularly when assuming a designer must find a form only after reaching a thorough understanding of the resolved function of an artefact; such is the pervasive view of a designer in popular culture.

2.2.1. Wicked Problems in Health

Design can be used as a way of approaching what Kunz & Rittel (1972) described as Wicked Problems. Such problems are distinct from 'tame' problems, such as Mathematical or Scientific problems, which are bounded, defined and have 'an answer'.

In their paper, the following criteria are set down as being indicative that the observed problem is Wicked:

- There is no definitive formulation of the problem. Every 'problem' can be considered a symptom of a higher problem
- The problem formulation is identical with problem solving
- There is a no stopping rule. The designer can always do better, and the design effort stops due to project finance or duration, not through a logical reason
- Wicked Problems are discrepancies between a realised solution and a situation as it ought to be. The solution relies on an explanation of these discrepancies. The explanation is rooted in the worldview of the Wicked Problem solver, and not objectively given.

The authors conclude that research attempting to propose a standard approach to identifying and solving Wicked problems is futile (Kunz and Rittel specifically mention Systems Approaches as problematic), instead efforts should be identified that seek input from people enmeshed in the Wicked problem, as it is their expertise that should be engaged in collaboration with the designer.

Complex scenarios can be broken down into three further distinctions; Wicked Problems, Messes and Tame Problems. A mess (Ackoff, 1997, p21, King, 1993) is a series of interconnected problems that cannot be solved in isolation. These require an interdisciplinary approach (as opposed to a single, siloed approach in a Tame Problem) to sort through the mess; to analyse patterns and understand how the 'here and now' will affect the 'there and later' (p106).

Healthcare is prone to these messes and Wicked Problems (Nelson, Salmon, Altman, & Sprigg, 2012; Raisio, 2009; Rosenhead, 1978; Showell, 2011), with design being well placed to tackle just such Wicked Problems (Buchanan, 1992). As mentioned in the sources above, the call for a joint inquiry involving all stakeholders and participants is required to come to an acceptable outcome. Participatory Design offers this possibility.

2.3. Health... and Design therein

Design in health means understanding the requirements of the healthcare sector- how is success measured? What outcomes are required? This means designing a study that integrates the appropriate evaluation techniques and collaborating with the appropriate people to facilitate the proper interpretation of the data. This does not mean that there are no issues of translation between design and health- on the contrary, the researcher has experienced first hand the misconception of design's (or, the designer's) role in a multi-stakeholder health design project.

With the dominant paradigm of healthcare being evidence-based, and the most highly regarded evidence in this domain coming from an objectivist worldview it is worth exploring the relationship that Design has with Science, and the connections that the two approaches share.

Rust (2007) talks about the need for shared language between designers and scientists[8], this might mean a move to explicitly discuss the forms of evidence used in design; or perhaps to be more explicit out the type of knowledge that practice-based design research creates.

2.3.1. Design and the scientific method

The pursuit of scientific research to produce new knowledge is a design activity (Glanville, 1999), since in the framing of a research question and the execution of empirical research scientists often act as designers. Driver, Peralta, & Moultrie, (2011) propose a mechanism by which Industrial Design might be included in scientific endeavour, based on a literature review, interviews with scientists (and engineers), and 3 case studies.

The inclusion of designers in the process of conducting scientific experiments highlights the value that design as a method of enquiry can bring. Designers stimulate the creation of new knowledge by producing artefacts to test ideas and aid understanding (Rust, 2007); bringing this to the healthcare sector (which is dominated by a epistemological paradigm informed by the natural sciences) could bring benefits beyond the development of existing prototypes, and beautification of graphic/print media. As is the researcher's own experience, the misconception that designers are purely concerned with the visual aspect of an artefact is pervasive (but not maliciously so).

At the Intersections 2011 design conference, David Kester of the Design Council presented his keynote address about using social behaviours to nudge people into action; as a way for complicated issues (Wicked Problems) such as obesity to be tackled, and how design, and in particular design practice could be used to tame these problems.

Kester used as an example the Design Council's *Designing Bugs Out* project tackling hospital-acquired infections to reinforce the idea of using design to create environments and products that not only were easy to clean, but that 'nudged' people into cleaning behaviours. The

[8] The Health sector works within an Evidence Based Medicine paradigm, which seeks to provide a body of clinically proven research at the disposal of medical / health practitioners to better support their practice.

project partnered clinical staff with design practitioners in an open innovation (Section 4.3, p 50) project, using design as a guiding methodology. One of the most successful project outcomes was the bedside table, developed from research conducted by KinneirDuort and Bristol Maid along with clinical staff.

The success of products such as the bedside table is attributed by David to the inclusion of design at the beginning of the development process; using design to reframe the problem, and bring 'fresh eyes' to help tame the complex and often interwoven aspects of healthcare and provision. Here, design is being moved on from the aesthetics applied towards the end of the development process, and used as an integrated methodology for a Wicked Problem.

This approach contrasts with the scientific method, outlined by Driver, Peralta, & Moultrie, (2012) which highlights the convergent nature of scientific research resulting in general laws, as opposed to a refined solution for design. This generalisation does not always provide an appropriate solution in terms of service provision for health services, as regional variations make for difficult implementations of central (generalised) approaches.

2.4. Evidence Based Medicine

> *"Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients"*
>
> (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996)

The current paradigm of the medical establishment in the UK NHS is the subscription to the notion that medical practice and interventions are based on empirical evidence, that the medical practitioner weighs against the presentation of the patient's condition. The chief model for the creation of evidence in a particular situation is the use of the Randomised Control Trial. This in turn has informed other health disciplines, creating a paradigm of Evidence Based Practice in healthcare, beyond medicine alone.

That evidence should be fundamental to the process of diagnosis is not in question (Goldenberg, 2006), but the type of evidence that medicine requires or specifies is set out in unambiguous terms as a hierarchy that is uniformly objectivist- that is to say the Randomised Control Trial is preeminent whilst expert opinion is valued least (Holmes, Murray, Perron, & Rail, 2006). Evidence Based Medicine seeks to replace 'Opinion Based Medicine' (Montgomery, 2005) as the dominant paradigm by emulating the mechanisms of the natural sciences. However, medicine is not a science (Hunter, 1996), instead medicine and medical practice is about negotiating paradoxes in practice. Holding these paradoxes in tension is a vital act of the practitioner in weighing the evidence available, and their own clinical experience of past cases (ibid).

This tacit knowledge of cases forms the basis on which clinician's act, but since this is not exclusively informed by (quantitative, but also qualitative) data this is labelled unscientific and viewed sceptically (Rycroft-Malone et al., 2004). In order for this practitioner experience to be folded into the canon of Experience Based Medicine, this experience should be externalised, to be critically reflected upon; known as affirmed experience (Stetler et al., 1998).

Evidence Based Medicine was not conceived as 'cookbook medicine' (Sackett et al., 1996) since the aim of Evidence Based Medicine is that the scientific data underpins the clinical intervention, and is used in conjunction with the clinician's experience. In their systematic scoping review Ubbink, Guyatt, & Vermeulen, (2013) highlight the recognition amongst medical practitioners[9] that Evidence Based Medicine is viewed generally as having a positive impact on health provision; although the practitioners also highlighted a range of barriers to adopting Evidence Based Medicine in their own practice.

The barriers listed present an interesting and continued debate- what is the best method for bridging the gap between evidence, research, and practice? Or, with one of the conflicts

[9] In their systematic review, the authors focussed on doctors and nurses' responses to a range of questionnaires in the papers reviewed. These papers took a global perspective, with a total of 10,798 respondents from 17 countries. Studies published before 2000 were excluded, since the authors highlighted that pre-millennial studies formed a nascent period in Evidence Based Medicine.

highlighted above as *conflicting evidence* (for both doctors and nurses) how might this evidence base be communicated in a way that facilitates dissemination and critical review by a practitioner?

2.4.1. Evidence Based Medicine and Design

If Evidence Based Medicine, and therefore Evidence Based Practice is the dominant paradigm by which research is undertaken in health, it seems appropriate to develop similar approaches for design, in order to better integrate design research into health research.

Evans (2010) highlights six different methods by which evidence is translated into medical practice. Evans describes these as 'filters' for the evidence, a method by which the practitioner can assess their rigour and applicability:

1. The *Systematic Review* of all evidence surrounding a medical condition / intervention. In the Evidence Based Medicine paradigm of today, Systematic Reviews of literature are respected as a useful research activity.
2. *Comprehensive pre-appraisal evidence*, based on a summary of the available evidence that comes prior to a Systematic Review.
3. A *Synopsis* of a particular piece of research, covering the methodological approach (including evaluation method) and giving an indication as to applicability to a certain type of patient.
4. *Systems Literature* – Guidelines for practice, evidence-based care pathways, and textbook summaries that are used to guide the care given to individual patients.
5. Written guides to health information sources
6. New websites aimed at disseminating information for use at the point of care. Some of these sites seek to offer 'pre digested' information in the form of bullet points (Evans cites Bandolier[10] (2008)).

As an Architect, Evans is concerned with how the medical paradigm of Evidence[11] informing practice can be applied to design. Evans begins by invoking Design Thinking as the method by which evidence can be applied to the design process. Design is *conjecture*, in that the process by which one designs is concerned with 'how the world could be' (adapted from Krippendorf, (2007)) rather than making a deep study as to 'how the world *is*' (*analysis*). This apparent incompatibility between the two focuses is mitigated for Evans by Design Thinking – that is, the multidisciplinary early prototyping of ideas in a participatory manner that is the

[10] See http://www.medicine.ox.ac.uk/bandolier/index.html for more information. The website Bandolier acts as a repository and summary of the Bandolier journal, published by Oxford University that specialises in the publication of papers about Evidence Based Medicine.

[11] The evidence base required of medicine is rooted in the scientific tradition of empirical evidence gathering, and positivism. This is distinct from a Popperian perspective on the scientific method. Falsification is not the same as positivism (Magee, 1974); rather it is the ideal mechanism by which scientific advances are made. Popper discusses the evolutionary aspect of scientific theories, and how they are comprised of tentative theories and subsequent work confirming or disputing some aspects. Positivism doesn't have the same evolutionary viewpoint, instead coming from an Objectivist worldview, establishing instead 'laws', or absolute truths. Popper is therefore Post-Positivist (Crotty, 1998)- yet while falsification is understood, scientists still do not widely look for falsification to 'established' theories (ibid). The positivist epistemology driving this assumption is perhaps counter to the notion of design; that is, a (participatory design) view that holds knowledge can be created in the collective act of making.

hallmark of the Design Thinking approach (Brown, 2009). In this, however, there are a myriad of different methods and tools that could be used to combine the analytical and practical approaches. Also, decision-making software, and other technology-based solutions are no guarantee of adoption and implementation of evidence (Marks, 2002).

2.5. Evidence Based Medicine – a critical view

In seeking to underpin healthcare practice with evidence, the creation of a way of measuring the 'quality' of evidence has drawn criticism from within the healthcare community. While Evidence Based Medicine is seen as having a generally positive impact on care (Ubbink et al., 2013), the exclusion or belittling of evidence from sources other than from the objectivist paradigm is 'outrageously excusatory' and 'dangerously normative' with regards to scientific knowledge (Holmes et al., 2006). This normative behaviour relates to the hegemony of the natural sciences (in health), and the privileged status that restricts practitioner's ability to publish studies and data not created in this paradigm[12].

Evidence Based Medicine also encounters problems when the evidence is not readily obtainable. For instance, with rare diseases the evidence base might not be up-to-date, and 'off-label[13]' uses of drugs not well documented (Darlenski, Neykov, Vlahov, & Tsankov, 2010). Continuing in their paper, Darlenski et al., also highlight the issues surrounding publication of papers for consideration in an Evidence Based paradigm, with those not using the 'gold standard' of a Randomised-control Trial passed over for publication (with a detrimental effect for the author's career).

The desire to improve medical practice with the rigorous application of evidence is not problematic in itself, but it appears that the pre-eminence of a certain type of evidence at the expense of others creates a hegemony that narrows the scope of inquiry, and denigrates practice and practitioner knowledge in an unhelpful way (Holmes et al., 2006; Hunter, 1996; Marcum, 2008; Montgomery, 2005).

Therefore, an appeal to 'Evidence Based Design' to facilitate better integration with health provision appears to be a chimera- Design should and indeed must include the relevant underlying methodologies and methods for evaluation and application into the field, yet as with medical practice these should not be at the expense of the practitioner's action. Montgomery (2005) discusses a Phronesiology of Medicine, that being the practical reason of the Doctor to select the best evidence, knowledge, and practice specific to an individual case; and that these actions are moral choices- the 'right' or 'wrong' choice in this context has real consequences for which the practitioner is ultimately responsible.

For 'Design' to be translated into a Health context, perhaps we should describe it in terms already used by practitioners of medicine – a 'Phronesiology of Design'.

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[12] Holmes et al., even go as far as to describe this effect as *fascism*, since it seeks to restrict other forms of knowledge other than it's own.

[13] 'Off Label' does not refer to illicit or illegal drugs for therapy, rather using a drug for a condition not originally intended to be treated with the compound.

2.6. Experience Based (co) Design

The introduction of design methods into healthcare provision has resulted in the Experience Based CoDesign (EBCD) methodology (Bate & Robert, 2007); Bate & Robert are not designers, but developed the methodology building from concepts and methods used in design practice and the Academy. The design consultancy ThinkPublic was commissioned to develop the materials and consult on the experience of using the methodology. EBCD is intended to facilitate a collaborative approach between healthcare providers and patients to redesign healthcare services. Placing the users of a service at the centre of the redesign effort is recognised as being central to both Healthcare and Design (Bate & Robert, 2006), and that Design therefore offers a 'rich corpus of knowledge' from which to draw inspiration (ibid). However, there is a recognition that often the ultimate measure of the success of a medical intervention is the clinical utility- rather than how it might feel to either deliver or receive such treatment (Pickles, Hide, & Maher, 2008).

Narrative forms a large part of the EBCD process, and in their paper, Bate and Robert demonstrate how their 'Experience Based Design' approach empowers the participants by lifting their input beyond tokenism and into implementation.

The EBCD toolkit provides the outline of the collaborative design process and suggestions for how to structure and organise the different meetings to gather data, design, and implement the changes.

The four stages of *capture*, *understand*, *improve* and *measure* are used to shape the project, and the toolkit calls for the appointment of personnel to 'own' and run the project (by inviting people to the events, ensuring tasks are completed- etc.). The whole project has an advisory board drawn up, comprised of volunteer patients, staff and carers. Capturing the experience of the service providers and users is imperative in more fully involving those participants in the design process. Dewar et al., (2009) describe the treatment of narrative, and whilst questions might be raised about the effectiveness of Discovery Interviews (as a means of eliciting narratives) with regard to interviewer technique or the treatment of the data (Bridges & Nicholson, 2008), in their implementation of EBCD the narratives were used to 'look again at what they do'- the reflexive practice that is at the heart of co design (Iedema et al., 2010).

During the *understand* phase, Experience Capture events code these narratives are then used as the basis for collaboratively defining the *touchpoints* of the health service, and the emotional states that the participant experience at (or during) their interaction with the service. This information is visualised using Post It notes on a timeline, with the x axis for *Time* (throughout the day), and the y axis for *Experience* (negative to positive). Specific activities throughout the day are recorded along the top of the chart.

These touchpoints extend beyond the confines of the Hospital building (Wolstenholme, Cobb, Bowen, Wright, & Dearden, 2010) to telephone calls confirming an appointment, letters from the hospital adding detail (items and information to bring to the appointment; how to find the correct entrance) to experiences with car parking, public and hospital-organised transport.

EBCD represents the forefront of an internal NHS attempt to use collaborative design to fuel change in health services. The methodology itself was heavily influenced by the design of services and experiences (Bate & Robert, 2007), and the methodology evolved into 'Accelerated Experienced Based Co Design'[14] the influence of *Design* in the development of this methodology is evident.

2.6.1. Case Study – Better Outpatients Services for Older People (BOSOP)

The BOSOP (Better Outpatients Services for Older People) project (Wolstenholme et al., 2010) used EBCD in reimagining an outpatient's clinic from the perspectives of older patients. The project was a collaborative effort, seeking to elicit ideas from all stakeholders acting on a level playing field in a similar vein to the participatory methodologies described in the next chapter. Within the broader context of the project, there were many seemingly simple problems that quickly became messes; with the introduction of socio-political strains from the bureaucratic nature of the National Health Service, these quickly became apparent as Wicked Problems. The project was intended as an evaluation of the EBCD methodology.

[14] AEBCD uses a library of video clips as a way of speeding up the process by which the participants understand experience.

EBCD focuses on the specific requirements of the health sector, where the *Improve &Measure* stages have a particular resonance with the Evidence-based Medicine environment healthcare practitioners inhabit. As such, this is a translation of the design process into a toolkit for non-designers, who could follow within a healthcare context to make direct and measurable changes to the environment and services within which they operate; and for those changes (however low-level) to have a measurable and positive impact on the service.

At the end of the BOSOP project, there were a number of outcomes that ranged in scope from changes to individual practice, altering the environment of the service, and wider hospital strategy (for example, vehicular access to the hospital building). A good example of the complexity involved in even the smallest of interventions is the redesign of the patient information letter. This letter formed one of the primary touchpoints for the older person accessing the medical outpatients' service, and yet from the CoDesign sessions it was found to be 'lacking necessary information, negative in tone and potentially confusing' (Wolstenholme et al., 2010). Once a series of design criteria was established from the CoDesign sessions and a prototype created, the idea was trialled. This proved more difficult than previously imagined, as the appointment letter generation had evolved from the intersection of different services (such as scheduling, and Yorkshire Ambulance Service), each one taken individually being a Tame Problem, but enmeshed in such a way with conflicting socio-political aspects that they produced a Wicked Problem; tamed by bringing these voices into the CoDesign sessions. The revised letter radically changed the layout and content of the text, making it more personable and easier to comprehend, with a photograph added to help identify the correct entrance to the hospital. Shown below are the two appointment letters, with the original letter on the left, and the redesigned letter on the right.

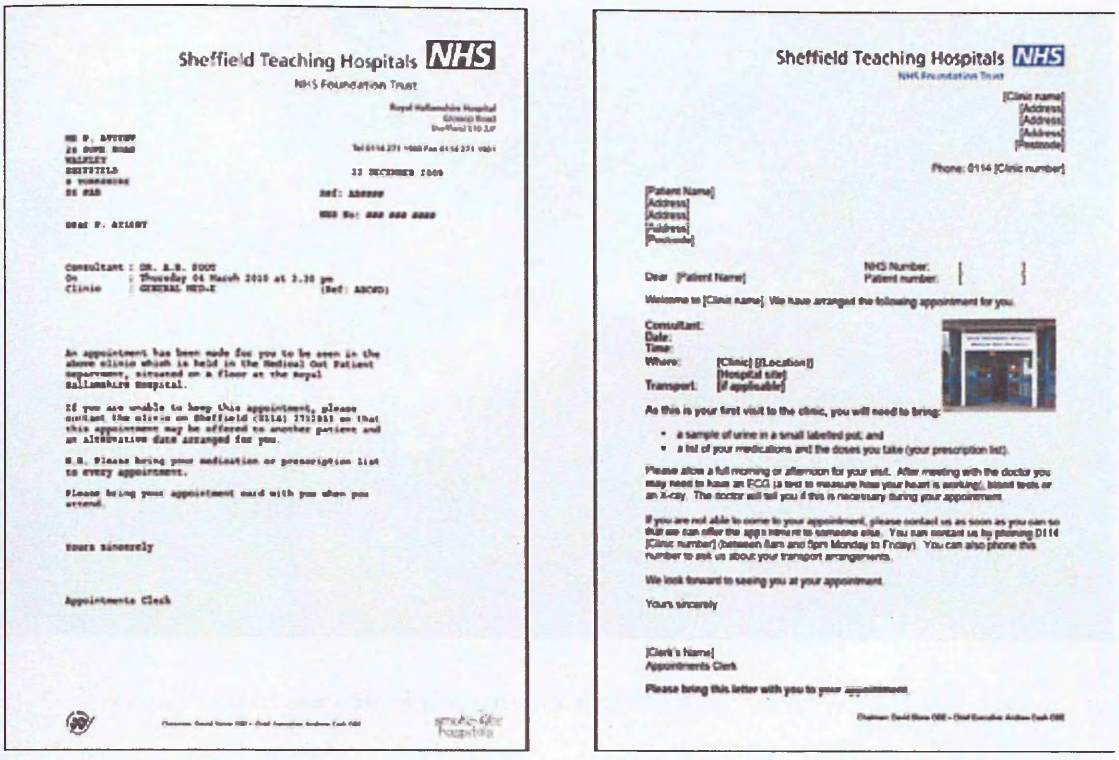

Figure 1 - Appointment letters from the BOSOP project; original left, redesigned right

Another output from the project was a problem highlighted by a number of different stakeholders, but that would typically have fallen outside of the scope of the health staff undertaking an EBCD project. The issue of road access to the Medical Outpatient's department was raised, as the private road (named 'A' road) proved to be an intersection for a number of complex, interwoven problems falling under different jurisdictions.

The road itself provides access to the perennially busy car park, taxi rank, disabled parking spaces, and drop-off area. The road was also used by the Yorkshire Ambulance Service to park non-emergency ambulances, and was intersected by three Zebra crossings. The 'A' road redesign is a good example of a problem that appeared complicated from the outset, but became increasingly so once an increasing number of factors and stakeholders were engaged in the process. The problem did not lend itself to an analytical approach, since mistakenly treating a Mess or Wicked Problem as a Tame Problem can make the situation far worse (King, 1993). As such, it was necessary to try and understand the whole (as best able) by engaging in a participatory prototyping activity with relevant stakeholders. As such, two designers, a Sister from the Outpatients' department, a patient's representative from previous CoDesign sessions, and a representative from the local city council's road planning participated in a collaborative prototyping session redirecting the 'A' road.

Figure 2 - Collaborative prototyping session for the Hallamshire Hospital 'A' road

As the prototyping session progressed, it became clearer where the boundaries of certain problems lay, and how a proposal for a reimagined 'A' road might look. As the session progressed, there were a number of solutions that had certain 'good' and 'bad' points to them, but a consensus was reached on the 'best' solution that held the different, competing problems in tension whilst also making some compromises that improved the situation for a greater number of visitors. This solution bears the hallmarks of an attempt to tame a wicked problem, by being interdisciplinary and not producing a binary solution to the problem.

The problems faced on the Medical Outpatient's service varied in complexity, and using the EBCD methodology it would be very difficult to evaluate which problems are beyond the scope of the team delivering the change. Similarly, the methodology does not include methods for deciding who might possess the skills required external to the team of people bought together (Simon Bowen, Dearden, Wolstenholme, Cobb, & Wright, 2011). In this sense, including professional designers (and embedding them in the delivery team) fulfilled these points, and the methodology was used for projects greater in scope than some EBD projects (Dewar et al., 2009; Kumar, Hedrick, Wiacek, & Messner, 2011; Tsianakas et al., 2012).

It should also be noted that the designers naturally gravitated towards high quality outputs, even during the participatory workshops (large-format maps printed on quality paper, choosing a well-apportioned room to conduct the meeting, etc.) to demonstrate the serious nature of the work, whilst also seeking the engender in the participants a feeling of their contributions being valid.

In tackling these Wicked Problems in a health context, and during this project it was when design as a profession was used in the ideation and concept stages of the projects that more radical solutions were proposed.

2.7. Chapter Summary

This chapter outlines the contribution that Design can make in health, with relation to the Wicked Problems that pervade the sector. Difficult challenges exist for the delivery of health services, which encompass a very wide array of components and touchpoints. These situations are prone to Wicked problems, which require a multidisciplinary, multi-stakeholder approach to propose viable solutions- and a participatory design approach is well suited to this task. Answers to a Wicked Problem are not 'true' or 'false', but 'good' or 'bad' (Rosenhead, 1978), with healthcare itself functioning more like an organism, than a linear machine (Raisio, 2009). Only with a participatory, collaborative approach that engages all relevant stakeholders is there an opportunity to tame the Wicked Problems (Kunz & Rittel, 1972) in health (Nelson et al., 2012; Raisio, 2009; Rosenhead, 1978; Showell, 2011).

Understanding and recognising the currently dominant paradigm of Evidence Based Medicine (and more widely, Evidence Based Practice) means that as designers we can (and should) tailor the design effort to include measurement, evaluation and implementation methodologies that recognise the requirements for quantifiable data, or specific outputs to measure the success or impact of an intervention.

This is not to say that design practice should seek to embrace a more *scientific* model of knowledge production; more that design should seek to describe itself in terms of *practice* to break down barriers between Design practitioners and Health practitioners. The concept of a Phronesiology of Design is important here.

Participation in the design process is important, and we shall see in the next chapter, this does not happen as a matter of course in medical product design. Genuine collaboration can be fostered in the development process, and the barriers to participation overcome by using Participatory Design methods.

3. Research Methodology

Design is not a science; yet it does not preclude the use of scientific methods. Similarly, design is not art[15]; yet it does not preclude the use of artistic methods. This apparent paradox sums up the practice of design- the weighing of evidence and the interaction with multiple stakeholders that is the hallmark of modern design practice. *Designing* is not to employ a methodology that will falsify a certain theorem or provide a new Law governing a phenomenon.

Design is concerned with how the world *could be*, rather than how it *is* – this important distinction highlights the way evidence is used in design, and how it differs from science. Design, like medicine or law is a practice; yet unlike medicine or law it does not hold a unique body of knowledge that an apprentice practitioner must train in. Any human is capable of 'doing' design, but some are professional designers- this distinction is a subtle one; a professional designer hones the artistic crafts that benefit the reframing of problems (such as sketching, modelling, prototyping, etc.) whilst also weighing and using the most appropriate evidence to use as a foundation for the enquiry.

Design research can be undertaken in three different ways; research *into* design, research *through* design, or research *for* design (Frayling, 1993). This thesis documents research *through* design- the research uses practice (design activity) in the building and testing of an open design project for the creation of medical products. The body of knowledge comes from the collaborative nature of design practice, with designers working with other people who each possess their own bodies of knowledge / lived experience.

A parallel can be drawn between the medical practice laid down in the *Design for Health* chapter and the practical design activity described in this thesis. Practical Reason – a Phronesis – is the method by which the practitioner acts based on an understanding of the evidence at hand and their own skill (or knowledge). The term phronesis comes from Aristotle's Nicomachean Ethics and is distinct from the episteme- the scientific method of knowing; *practical* reasoning is useful when the circumstances are changeable, or not readily able to be generalised (or where they are context specific) (Hunter, 1996; Montgomery, 2005).

Design can be 'done' by any human, but is practiced professionally by few- those few practitioners must work with evidence in the field they find themselves in, whilst also combining this with evidence brought in from outside the problem to broaden the scope of the project (Harfield, 2007).

[15] Art is the pursuit of beauty- the creation of an artefact for it's own sake. Design is creation in response to some external stimulus. Art explores & creates for it's own sake; Design explores & creates as a response to the world.

In this case, research through design can be viewed as a Phronesis (as with medicine[16]), instead of a singular epistemological position[17]. Design as Phronesis is the position for this thesis; the design activity here is framed as the practice of choosing the most appropriate research methodology (and therefore the right methods and tools) for the study. This phronesis does not limit the designer to a hierarchy of acceptable evidence- rather it allows for the selection of a methodology or theoretical perspective that most appropriately fits the inquiry.

In this chapter, as in the thesis as a whole, the term 'design research' refers to research through design practice; and the use of the term *design* refers to a collaborative, participatory process involving multiple participants in the research; the artefacts created embody the knowledge from a multitude of voices working in concert.

3.1. Design as Research

The introductory chapter of this thesis briefly lays out the state of Open Design as we find it today, and therefore what research methods are most appropriate to try and answer the research question- How can people who are barred from Participatory Design through living with a chronic condition be included in the design and development of medical products?

For instance, if Open Design were a mature, and much-practiced branch of design then an anthropological study, using ethnographic methodologies to identify and record the minutia of an aspect of the process would be appropriate. Similarly, a Delphi method could be used to highlight a 'snapshot' of current expert opinion amongst open design practitioners (Dalkey & Helmer, 1963).

However, while the foundations of open design are old, the modern implementation based on Distributed Digital Manufacture (section 4.4.1 p 54) across the Internet is new. So new in fact that there are few mature entities producing artefacts (in comparison to other industrial design methods). Using open design in the production of medical devices, or even prototype devices is not currently practiced- there are no open source (hardware) medical devices on the market today. With the paucity of devices and manufacturers (or even designers) this limits the scope of any research based on such anthropological methodologies.

Similarly, a systematic review of design papers for open design in medical product development is problematic, not least because there is currently a lack of underlying theory to the practice of design research. However, as we saw from the Design in Health chapter the reason behind this lack of underlying theory in design is not necessarily a disadvantage; as with medical practice, design practice (and therefore research based on design) can be

[16] When discussing Phronesis, Montgomery (2008) relates this to physicians (doctors). However, the practical reason described by Montgomery is applicable across many fields (Engineering, Law, etc.) and as such the idea of phronesis also applies to evidence-based *healthcare*. Allied Health Professionals would therefore also use phronesis in their practice.

[17] This means that there is not a single prescribed epistemological position from which research through design is conducted. There is currently debate amongst the design research community about whether there *can be* a fundamental underlying epistemological position for design (whether this is an Objectivist, Relativist, etc.).

seen as a Phronesis, drawing upon different epistemological positions where necessary, and appropriate (Montgomery, 2005).

3.1.1. Rigour

> *"One has to ask: Was the activity directed towards the acquisition of knowledge? Was it systematically conducted? Were the findings explicit? Was the record of the activity 'transparent', in the sense that a later investigator could uncover the same information, replicate the procedures adopted, rehearse the argument conducted, and come to the same (or sufficiently similar) conclusions? Were the data employed, and the outcome arrived at, validated in appropriate ways? Were the findings knowledge rather than information? Was the knowledge transmissible to others? Only when the answers to all these questions are in the affirmative can a practitioner activity be classed as research."* (Archer, 1995)

As Archer (1995) discusses, for an activity to qualify as 'research' there are criteria that must be satisfied. The work must be conducted systematically, to suitably rigorous standards and following a plan; to have knowledge as its goal, rather than mere information; to communicable in some fashion to an interested third party.

This definition of research cuts across disciplines, and is equally applicable to the natural sciences and the humanities. According to (Cross, 2007) design represents a third discipline, with it's own knowledge production and dissemination. As Leadbeater (2009) highlights, Research is thought to consist of lab coats and clipboards- usually performed by a scientist; the view of the professional individual being the source of innovation or scientific advancement[18] (the 'boffin in the lab' troupe).

Design is concerned with making things, and as Pallasmaa (2009) discusses in *The Thinking Hand* cognition doesn't simply reside in the brain. Drawing as collaboration between the head and the hand results in knowledge being formed- knowledge about a building, or a sculpture for instance. For Cross (2007) objects, and the knowledge that resides in them are a 'significant branch of designerly ways of knowing'.

As the quote from Archer (1995) above highlights, simply producing 'designed' objects does not count as research. As such, design as research requires that knowledge is created and disseminated- and that in creating artefacts, these form part of the knowledge-directed enquiry. In Gaver & Bowers' (2012) review of their own projects they discuss the use of guiding methodologies and theories to instil 'rigour' in the methodological process for designerly research, possibly leading to a tighter alignment with the HCI field that Gaver & Bowers work in.

[18] Such a view belies an enlightenment-era view of science as empiricism and rigid objectivism, giving rise to positivist methodologies and methods such as the Randomised Control Trial. However, this view is incongruous with the 20th century developments in the philosophy of science from Popper, Khun and Polanyi.

In seeking to appropriate other methodologies to fit design into, they argue that theoretical perspectives and guiding principles promise results that are applicable in a more general sense (as with the natural sciences); however there is also the possibility that these stifle the practice of design:

> *Methodological frameworks promise rigor but jeopardize the possibility for designers to invent ad hoc approaches, or draw inspiration from unorthodox sources, or take inexplicable imaginative leaps—all forms of a productive indiscipline that we see as integral to design practice.* (Gaver & Bowers, 2012)

Creating artefacts in design practice embodies the knowledge of the collaborators (or solo design practitioner) in that artefact, since drawing, modelling and prototyping can all be taken to be *thinking* (Pallasmaa, 2009). In his account of piloting a US Navy vessel into San Diego harbour, Hutchins (1996) discusses the role of the cartographic equipment, and the various seamen or officers whose roles were all instrumental in guiding the vessel to port. That the cognition is distributed across the different equipment and actors in the process is important; in collaborative design, the knowledge does not simply reside in the objects– the knowledge is distributed across the people who collaborated in that development, and the artefacts produced. However, this embodiment of knowledge is not enough on it's own to constitute research- the systematic execution of an enquiry with transmission of knowledge to others (via an appropriate theoretical framework) is research (Archer, 1995; Glanville, 1999).

An example of an activity that is knowledge directed (to use Archer's terminology) is science[19]. The Objectivist world of basic science deals with the formulation of theory, and the rigorous testing of individual variables to obtain data. This data is weighed against theory, and general theories are produced as explanations to the phenomena under scrutiny.

Polanyi (1966) introduces the idea that the scientist cannot be completely removed from the science; that the tacit knowledge of a field yet unexplored comes from the deep knowledge and association with a particular field. Cross (2007) discusses the differences between Inductive and Deductive reasoning, and while design might include both of those steps in the act of *designing*, fundamentally design concerns abductive reasoning.

Science and design share an abductive step, although it would be wrong to define either endeavour solely in this term. Inductive and Deductive reasoning also plays a keen role. For Cross (2007), design as a discipline should be viewed as separate from the humanities and

[19] In the previous chapter, the differences between the scientific and the designerly approaches to research were introduced. This served to highlight the similarities between research carried out in medicine (within an Evidence Based Medicine paradigm) and the more general view of scientific research. In medicine, the perception of science as a Positivist, empirical (Baconian) endeavour persists (Hunter, 1996; Montgomery, 2005)- Montgomery likens this view to the position adopted by the mass media when discussing scientific *Laws*- these are intractably tied to enlightenment notions of science, rather than the 20th century notions of *Falsification* professed by Popper (Magee, 1974) and Tacit knowledge (Polanyi, 1966).
The concept of a Law in science belies the Positivist viewpoint from which the theory underpinning the Law came- Laws are intractable, unchanging, fixed; this suggests an objective reality that is *true*. This Law is confirmed by the adding of empirical data that confirms this hypothesis (Inductive reasoning). However, Falsification holds that adding data to the theory does not confirm the Law, rather seeking to find conditions that the Law does not hold in gives more specificity, more knowledge. It is this seeking to specify that is the evolutionary engine of scientific endeavour according to Popper. A famous example that highlights this notion of falsification is the statement that 'all Swans are White'.

sciences. Cross posits (p18) Design has as it's phenomenon of study *the artificial world*; science *the natural world*. The methods in design *modelling, pattern-formation* and *synthesis*; science as *controlled experiment, classification, and analysis*. Finally the values for design as *practicality, ingenuity, empathy* and a concern for *'appropriateness'*; science as *objectivity, rationality, neutrality* and a concern for *'truth'*.

If the creation of artefacts does not produce research, even when the knowledge is created (and distributed across the collaborators, their environment and the artefacts), then the production of these artefacts must be directed to produce knowledge that can be disseminated. As per the criteria that Archer (1995), Frayling (1993) and Glanville (1999) lay out, this practical action must be recorded to facilitate independent verification. This ensures rigour, and means that the design activity can count as research. Frayling outlines 3 different states for research and design:

- Research into Art and Design
- Research through Art and design
- Research For Art and Design

Since there are no companies or entities using Open Design for the development of medical products, then the opportunities for research *into* this approach are greatly diminished.

This research instead falls into the second category, with a slight appeal to the third; by applying collaborative design practice in a prototype community and recording the results, an answer is recorded to the research question. The outcomes of this research could also inform practice in Design.

3.1.2. Design Practice in Design Research

Although not constituting research in itself, the practical outworking of a research project using design methods is a valid course of action. Sheffield Hallam University has a pedigree in this method, with notable alumni using this approach to great effect. Whiteley (2000) uses design practice to great effect in producing a robotic hand that behaved in a lifelike manner. The extensive use of drawing, as well as prototyping early in the process enabled this complex and influential piece of work- building a lifelike mechanical robotic arm was a seemingly insurmountable challenge, but Whiteley's use of design practice enabled him to produce a solution (Atkinson & Zhi, 2011).

Similarly, Bowen (2009) used design practice as a method of developing his *Critical Artefact Methodology* with different groups of workshop participants. The designerly qualities of his practice were instrumental in the development of this methodology.

3.1.3. Production Values

Discussed in chapter 5 (Section 5.2, p 83) is the scoping work undertaken by the researcher prior to the main case study. A key personal finding from this work was the reactions to the work of the designer (and other designers involved in the work) by other stakeholders

involved in the projects. Notably, the appreciation of the seemingly small details like props for collaborative workshops, or the production of high quality printed materials for dissemination of collaborative work.

The obsession over details, the perfectionism present in much of the researcher's practice and experience is called out by Sennett (2009) as a sickness. Yet, in driving up the quality of artefacts for eliciting a reaction in a workshop, or engendering participation in an event the feelings evoked by the use of high quality artefacts should not be overlooked – perfectionism as a positive trait, rather than an apathy that is satisfied with 'good enough'. Presenting someone (perhaps a potential participant in a workshop) with a well produced, thoughtful artefact allows that person to take the project seriously, to feel his or her contribution is valued and important.

3.2. Action Research, and Design

> *The philosophers have only interpreted the world, in various ways; the point is to change it.*
> *Karl Marx, 1845*

This research is framed as Action Research. The structure of an Action research enquiry means that knowledge is created through 'testing hypothesis with practitioners in real situations, gaining insight and feeding back into the process' (Avison, Lau, Myers, & Nielsen, 1999). Therefore, the work is iterative and cyclic, with periods of action and periods for reflection. This combination of activity requires adequate documentation; it is crucial that the work is documented in a clear and transparent fashion in order to satisfy the requirements laid down by Archer (1995) for the activity to constitute research (Checkland & Holwell, 1998). Since it is impossible for research in the Arts to be entirely objective (as discussed by Archer, ibid- and neither should such generative research be), then it is equally important that I record all assumptions and thoughts before the action takes place.

Reason & Bradbury (2005) might take issue with the label 'Action Research', since the design of the study (i.e. the formulation of the original research question) was started before the participants joined the space. Whyte (1989) discusses the requirement that the participants be involved in the development of the research questions and direction from the inception of the project for the research to be appropriately defined as Participatory Action Research. However, Participatory Design and Action Research share many deep, fundamental attributes making the label 'Action Research' appropriate for this research.

Action Research is about changing the situation of the people involved in a specific time and place (Bødker, Nielsen, & Orngreen, 2007); in demonstrating a contribution to knowledge this research therefore centres around a specific case study, documenting the participant interaction and providing the basis for reflection and acting as a public record of events. Breslin & Buchanan (2008) write that the formal case study structure can be seen as an application of the design process, and as such it fits well with the idea of using Action Research for this design enquiry. By this mechanism, the work on this PhD fits the

description of research by practitioner action given by Archer (1995). Also discussed by Archer is Action Research, and it's application in design research. However, with Action Research, the researcher recognises their part within the research, in this respect Action Research differs from the natural sciences- it is concerned with understanding how the world could be, rather than how we find it.

This position is consistent with the epistemological foundation of the research involving the participants- for instance, when making sense of the life one leads with a chronic disease, working in a collaborative manner with people who live with a chronic illness, this is Social Constructionism (Crotty, 1998). The research moves past this – with the sensemaking directly informing the creation of artefacts in a collaborative design project; a realist endeavour. In undertaking this research, the standpoint of the researcher must be made clear. This is important, as the researcher does not share the lived experience of the participants with a chronic disease; this research has a moral dimension also, seeking to empower people previously disempowered from being part of the design process. Feminist Standpoint Theory (Bardzell & Bardzell, 2011; Bardzell, 2010) grounds this sensemaking, and is compatible with the aims and objectives of an Action Research methodology.

Standpoint theory (Bardzell & Bardzell, 2011) is an epistemological position which recognises the researcher's 'physical location in nature', the 'interests in and about that location', the 'Discourses that shape the sensemaking concerning the location', and 'a position in the social construction of knowledge' (ibid). The focus on the experiences of the marginal is key to Standpoint Theory, which chimes with the democratic, emancipatory roots of Participatory Design, and Action Research- the research described in this thesis seeks to empower people with cystic fibrosis to be part of the design and development of medical products (an activity they are currently barred from).

The researcher's position is carefully recorded before the research, the research is recorded as it proceeds and the notes made available for scrutiny, and the findings are weighed against the recorded work and the initial preconceptions. In this way the design research project constitutes valid research. This position is my *standpoint*- my frame of reference from which I view the world.

This therefore aligns well with the theoretical and historic positions outlined in Participatory Design (Abelson et al., 2003; Carroll & Rosson, 2007; Kensing & Blomberg, 1998; Simonsen & Robertson, 2012; Spinuzzi, 2005), Action Research (Checkland & Holwell, 1998; Hayes, 2011; Reason & Bradbury, 2005) and Feminist Standpoint Theory (Bardzell & Bardzell, 2011; Bardzell, 2010).

To further ensure rigour in the application of an Action Research methodology a framework to highlight the structure and process for the research is required. Checkland & Holwell (1998) outline the key elements to any piece of research; The Framework of ideas (**F**), the Methodology (**M**), and the Area of concern (**A**).

The Framework of ideas (F), Methodology (M), and Area of Concern (A) can thus be articulated at the beginning of the project, to ensure that the work can be considered research (for an outline of the F, M and A for this PhD study, see section 5.3.1 p 88).

The structure of an Action Research enquiry is circumvoluted, with the whole research activity comprised of Action Cycles (themselves comprised of Planning, Action, and Reflecting activities). These might not happen in distinct phases, but will all be present in an action cycle.

These Action Cycles constitute the research process, and are the engine that drives the research activity. In section 5.3.4 (p 91), the Action Cycles that make up the main case study are recorded. The decision to exit the project and write up is decided as part of the planning phase, but within the Action Cycle structure this can be reflected upon, and modified as per the needs of the study.

3.3. Methodologies of research, and practice

As previously stated, this work uses Action Research as an overarching methodology to guide the research activity. This involves the description of preconceptions and bias that the researcher holds, whilst also adequately recording the process of the research to demonstrate rigour. This approach means that the research can be verified and inspected by other interested parties- this transmission of knowledge (as opposed to mere information) is the hallmark of research (Archer, 1995).

The practical work is also guided by Open Design – this collection of methods of designing appears at first to be the Area of Concern (Checkland & Holwell, 1998); but it also guides the methods by which the action is carried out. It is also important to highlight the concerns of Gaver & Bowers (2012) that fitting the design process too firmly into methodologies from the natural sciences or the humanities risks stifling the design activity (Cross, 2007). As such, I am mindful that this implementation of Action Research might be considered by some to not be a purist's implementation.

However, research through design (particularly with respect to participatory design) shares a similar ontological stance with Action research; both seek the collaborative act of *doing* in order to enact *change*- both are concerned with how the world *could be*.

3.4. Participation in Design

As previously mentioned in the Design for Health chapter, Participatory Design is an important method for ensuring that people are included in the research that will affect their lives. These participatory notions are aligned with the epistemological position of Action Research (Reason & Bradbury, 2005). Indeed, one distinct application of Action Research is Participatory Action Research (PAR). Participatory research is described as not simply 'a convenient instrument for solving social problems' (Park, 2012), but also 'a social practice that helps marginalized people attain a degree of emancipation…' (ibid).

Design has seen the development of a large body of knowledge about how to include different stakeholders affected by the development of new artefacts. This corpus of knowledge is shared with different disciplines in the Computing paradigm (Human Computer Interaction (HCI), Computer Supported Cooperative Work (CSCW), End User Design (EUD), etc.), and means that Design as a method of enquiry and production has a significant contribution to make in the development of new health artefacts (services, products, care pathways, etc.).

3.4.1. Participatory Design

> *'Design is a personal activity and springs from the creative impulse of an individual. Group design or design by committee, although occasionally useful, deprives the designer of the distinct pleasure of personal accomplishment and self-realization. It may even hinder his or her thought processes, because work is not practiced under natural, tension-free conditions. Ideas have neither time to develop nor even the opportunity to occur. The tensions encountered in original work are different from those caused by discomfort or nervousness'.*
>
> (Rand, 1993)

Two years previous to Paul Rand's quote (above), Ehn & Kyng (1991) published their paper on the collaborative design of computer systems for the printing industry in Scandinavia; the antithesis of this idea of the lone genius being the sole impetus for a successful project outcome.

At its heart, the notion of Participatory Design is the democratic value that those affected by the output of a project are entitled to have a say in that project, with an emphasis on the emancipation of resource-poor participants in the process of engaging with policy makers, or changing work conditions. Participatory design is an ideological stance, growing from the political milieu of the 1960's and 1970's, which shared similar ontological, ideological and ethical foundations to the nascent Participatory Action Research methodology (Hayes, 2011), which was developing at a similar time (Reason & Bradbury, 2005).

Arnstein (1969) wrote about the degrees to which a person is empowered to effect change on a piece of policy, and this influential piece of work lays out the degree to which a person can be involved in a piece of work.

While not describing eight states of being with distinct boundaries that can be precisely measured in a real world context, the real value of this idea is to demonstrate the states of participation that can exist; the 'powerful' and the 'powerless' are not homogenous groups (ibid). This paper helps to frame the positions different stakeholders play in the process of developing medical products.

Indeed, Ehn's work with Scandinavian publishers was intimately connected to the respective profession's trade unions (as they were stakeholders in the project, along with industrialists and 'shop floor' workers). Writing reflectively on Participatory Design from the 1970's and 1980's, Ehn & Kyng (1991) observed that when the varied stakeholders (including designers) were not brought together to engage in the design process, the eventual users of the product were unable to create 'visions of future working conditions and practices' that even matched the current status quo; still less exceeded them. It can be shown that participation of multiple stakeholders in the design and development of products can produce products of verifiable quality; whilst also emancipating those involved (Noble & Robinson, 2000), and leading to further participation, as people *feel able* to have an impact on their circumstances (Müllert & Jungk, 1987).

However, Stickdorn & Schneider (2012) talk about the importance of not just user participation, but co-creation as a vehicle for producing quality. This collaborative way of working is changing the landscape of design practice (Sanders & Stappers, 2008) with designers gradually working more and more closely with those who will use their products. Collaborative Design is not the only paradigm by which people can be included in the development of products- more consultatory methods can be used. For instance, User-centred design involves the consultation of users via appropriate methods to inform the design process, but not necessarily as partners. This process formed the basis of my Masters study (section 1.1.16). In mapping the territories of collaborative creation, Sanders & Stappers (2008) highlight different paradigms that demonstrate the relation of different methodologies along 2 axes- the degree to which a methodology treats the user as partner or subject, and the degree to which the lead is research or design (practice).

Arnstein's (1969) Ladder of citizen participation here acts as a useful framework through which to view the *x*-axis on the co-creation landscape. The further towards 'user as partner' one travels, the further 'up' the ladder of citizen participation one moves. This thesis describes work led by design, and as such the focus on the use of design practice in an Action Research framework means the case study described in chapter 5 exists in the upper right quadrant of Sanders & Stappers' (2008) framework (shown below).

As per Sanders & Stappers' paper, the work carried out by the researcher during the Masters degree with Stroke survivors (section 1.1.1 p 6) constitutes User-centred design. The Focus group attendees were able to give their feedback on the designs, but not fundamentally alter the direction of the project. Their insights created a *better* set of designs (as measured by the criteria of the healthcare professionals), but did not mean that the system itself was open to

critique. This ability to have a say in the direction of the design process is the hallmark of 'genuine participation' (Arnstein, 1969; Hess & Pipek, 2012; Kensing & Blomberg, 1998; Luck, 2007).

3.5. Participatory Design in Medical Product Development

> *'Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*
>
> *-diagnosis, prevention, monitoring, treatment or alleviation of disease*
>
> *-diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
>
> *-investigation, replacement or modification of the anatomy or of a physiological process,*
>
> *-control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means'*
>
> *EU Definition of a Medical Product - Article 1.2 of Directive 93/42/EEC*

There are benefits from including users the development process for medical products including; reduced cognitive overhead (devices are more intuitive), error-in-use reduction, improved health outcomes, increased user satisfaction, access to personal experiences and insights, reduction of development costs, and a reduction in post-release device recalls (Henninger et al., 2005; Martin & Barnett, 2012; Shah et al., 2009).

Different stakeholders are included in the design and development of medical products, with the end users forming part of this mix (Karlsson et al., 2011; Shah & Robinson, 2006), and perhaps even pre-users[20] (Kelly & Matthews, 2010). User involvement is most concentrated in the initial stages of the design process, with recognized benefits for saving costs that would be incurred redesigning products that are not appropriate. Shah et al., (2009) propose a framework for including end users (and professional users, such as clinicians, surgeons, etc) - outlining different methods that might be employed including stakeholders in the development process.

Participation does not happen as a matter of course, and the medical device industry has been slow to include the user in the design and development process (Henninger et al., 2005; Karlsson et al., 2011) However, it would be disingenuous to suggest that all medical device producers exclude users from their design and development process entirely- especially as the evidence does not back this assertion (Shah et al., (2009), Wilcox, (2010).

[20] A 'pre-user' is described as someone who has not yet been prescribed a medical device to manage their condition, but is likely to be a user in the future. For instance, Kelly & Matthews (2010) worked with people who lived with Diabetes, but did not themselves use a particular device for managing this condition.

Using Arnstein's (1969) *Ladder of Citizen Participation* as a classification tool it is possible to show that these activities do not constitute collaborative working, with the activities described in the framework being more consultation, rather than delegation or a shared power in decision making (collaboration). For instance, *'3. Discussion with users'* does not prescribe that the outcomes of these discussions even be acted upon, much less an attempt to embed the lived experience of the users into the product development. The methods listed are; Brainstorming Sessions, Cognitive walkthrough, Discussion with users, Ethnography, Expert user meetings, First human use, Focus groups, In-vitro tests, Interviews, Observations, Surveys, Think-aloud method, Usability tests, Users-producers seminars, and user feedback.

The framework here represents a step towards the conditions described by Sanders & Stappers, (2008) with producers moving closer to their future users, but as per the work of Money et al., (2011) shows the methods for including users fall short of genuine participation in the process, and could not be considered participatory design. They can be plotted on the landscape proposed by Sanders & Stappers, (2008) in the lower-left quadrant; that is to say, they are more focussed on the 'user as subject', and are 'led by research'- with less focus on generative, participatory, practical design methods (as highlighted by (Shah & Robinson, 2007)).

Some elite design consultancies deploy a rich mix of ethnographic and inclusive design methodologies to develop their products (Wilcox 2010), with specific examples receiving prestigious design awards for their conception and operation.

As we have seen, there is a moral case for pushing for greater user collaboration in the development of products generally, and especially so for a product that a user requires to maintain their quality of life.

In seeking to better understand how a design participant views the design innovation during the development process of new medical devices, Lehoux et al., (2011) expand on the 'object world' of Bucciarelli (2002) to explore where design participants position themselves in relation to the creation of new medical products, and how they bring different contributions to the design process. Object worlds are defined by Bucciarelli (1996) in his book *Designing Engineers:*

> *A naïve empiricist would sense its weight and estimate its size: another reader might note its colour or texture; a chemist on the design team would describe its resistance to discoloration, its acidity, and its photosensitivity. A mechanical engineer would be concerned with its tear or its tensile strength, its stiffness, and its thermal conductivity. An electrical engineer would speak of its ability to conduct or to hold a static charge. All of these attributes of the object, the same artefact, are understood within different frames of reference, and they all might contend in a design process.*

This description allows us to imagine or define the position that a partner in the design process will be concerned with[21], yet also recognising that the person will view the innovation through their own 'lens' (or lenses) stemming from their own ideological, theoretical, theological or even experiential stance(s) (Harfield, 2007).

The conceptual framework of Lehoux et. al, is outlined below, showing the position of the design participant with relation to the medical product manufacturer, and the worlds of the other collective designers.

The framework shows that design participants in multidisciplinary environments are able to experience other worlds from the perspective of those inhabiting those worlds- crucially, the authors highlight 3 specific instances of participants viewing (or interacting with) other participant's worlds from their case studies:

1. Building a new innovation by assembling the pieces for an 'entrepreneurial world'
2. Searching out pieces from other worlds, and assembling them as something new for their *own* world
3. Migrating from their own world, to build within another- thus taking an innovation elsewhere to create a better 'fit'.

Another finding is that a *lack* of knowledge on behalf of a design partner can 'trigger a co design response'- by pushing the design partner to seek out more information or input from another object world inhabited by a different design partner. This work recognises design as a social process (Cross & Clayburn Cross, 1995), linking back to the theoretical perspective in this thesis of the socially-constructed sensemaking in the Participatory Design of an artefact, as considered research through an Action Research methodology - and therefore the role that participatory design can play in the development of medical products.

These examples show the positive aspects of including users in the design and development of medical product development- with award winning, successful medical products created using a combination of user-involvement methods. These range from consultation through to participation- yet why is this not the case across the industry?

3.5.1. Barriers to participation – a manufacturer's perspective

Many medical device manufacturers do not include users because of the perception that these methods are too resource-intensive, or that the companies themselves do not have the resource for a 'human factors' approach (Karlsson et al., 2011; Money et al., 2011), since user compensation (for participation) is particularly singled out as a barrier to user inclusion (Weigel, 2011), although a barrier that continues to be mentioned is the availability of users to participate in user-involvement sessions (Karlsson et al., 2011). Also, companies should be willing to allow the development process to move from the initially defined course to achieve

[21] Lehoux et al., end their paper by highlighting the limits to their research, with a particular emphasis that more research into people with multiple specialities could yield interesting results with regard to studying Bucciarelli's object worlds as used by Lehoux et al.

the most successful outcome (Owens et al., 2011), recognising the benefits that this brings to the process.

3.5.2. Barriers to participation – a participant's perspective

The barriers highlighted above also intersect with the barriers for people who wish to participate in the participatory design project. For instance, there is a cost involved with participation, in that it requires a participant's time to be part of the design activity (Müllert & Jungk, 1987) – even if they are reimbursed for their travel. This also assumes that the participants *are able* to join the design activity- some people who live with a chronic condition have a reduced capacity to participate. Their condition might render them immunocompromised, meaning they are barred from meeting others who share their condition (as is the case for people living with cystic fibrosis); they may have a rare condition, meaning that there are large distances between individuals (making the cost prohibitive); their condition might be taboo- in which case there might be a reluctance to share personal experiences.

3.6. Design Thinging

There is a differentiation between the designing of an object (a 'thing'), and a socio-material construct- a 'Thing' (Bjögvinsson, Ehn, & Hillgren, 2012). For instance, a 'Thing' in this concept is the design *project* – it has boundaries, timelines, deliverables, etc. (ibid). Necessarily, this 'Thing' includes human and non-human elements that together form the environment, or tools by which mediation and mutual learning occur. For instance, the venue that a future workshop (Müllert & Jungk, 1987) might take place in, the notes taken on the flip-charts, etc.

Participatory Design is a fundamentally collaborative act of making; and in the making- that this is envisioned and prototyped early on (Ehn & Kyng, 1991; Spinuzzi, 2005). Design Thinging is not solely concerned with engagement in Participatory Design- i.e. 'use before use' (participatory workshops, and collaborative prototyping to with partners (Morten & Kyng, 1993)), but also a move towards *infrastructuring* (Pipek & Wulf, 2009) in design projects, rather than focussing on the *projecting* – that is, that there is consideration for 'design after design'; the participants in the process are enabled to continue designing beyond the project boundaries.

Such meta-design (Fischer & Scharff, 2000) breaks down the sharp separation between the creation and use of the system. For participation in design, this means that the participants have more freedom to take ownership of the process, and to guide development further.

Design after design involves participating in design Things separated by time and space- the infrastructuring of this space (public Things, ibid) is important, as it relies upon the relationships that form between the design Things during the project time, and the many potentially controversial design Things in use- infrastructure is also shaped by the participants as well as designers – sometimes acting as mediators, sometimes interpreters and sometimes articulators.

Participatory design is a worthwhile endeavour, especially in health. The democratic, and emancipatory aspects are of particular benefit to the users of medical devices, and the benefits for other stakeholders (such as a user's increased adherence to treatment regimes, which would benefit clinical staff; or the inherent desirability of a medical device designed with these participatory principles in mind, benefitting a manufacturer) vouch for this method. The principle of rapid, early-stage low-fidelity prototyping aligns well with the principles and techniques of a participatory approach. Similarly well matched is the idea of enabling (or encouraging) design by non-designers.

Finally, Design Thinging introduces the idea of 'design after design', that being the necessity of structuring design interventions that can move beyond the scope of the original design project, as a traditional Participatory Design project cannot involve all possible users, or use scenarios for a particular artefact. This approach appropriates meta design, and the infrastructuring of projects to allow for reconfiguration by the project partners.

3.7. Chapter Summary

From the previous chapter we saw the problems inherent within health provision, which often tend towards Wicked problems. Design is a good way of approaching these, since multidisciplinary, multi-stakeholder approaches are a good approach to taming Wicked problems.

Participatory Design can be used to tame Wicked problems, and the state of participation in medical product development has been laid out in this chapter- along with the state of Participatory Design in medical product development. The challenge comes in extending the design space out beyond the original design project boundaries. This infrastructuring of the project requires a different approach to traditional Participatory Design, and as Press (2011) discusses, the challenge to the design profession is how best to aid in harnessing the power of this collaborative approach (the 'crowd'). This requires that the approaches remain emancipatory, empowering and therefore 'genuine' collaboration (Hess & Pipek, 2012).

This PhD thesis relies on the collective sensemaking of the experience of living with a chronic condition, rooted in a Social Constructionist worldview. This knowledge about the condition, is then used as the basis for a collaborative design project as a realist endeavour. In order to constitute research, this work is guided using Action Research, with the researcher's *standpoint* recognised as integral to the findings recorded.

In the next chapter, the methodology of practice known as Open Design is outlined as an opportunity to enable a distributed, participatory approach to the design of medical product prototypes that offer the potential for 'design after design'; as in, their infrastructure allows for the continuation of the design process beyond the initial design project's scope. This approach also allows for those who are barred from participating in the design activity to be included at collaborators, as the work is facilitated via the Internet.

4. Open Design

4.1.1. Introduction

This chapter describes the current state of open-source design, in relation to the production of open-source objects. The field is nascent within the wider paradigm of design practice, but set to grow as the development of Distributed Digital Manufacturing (e.g. 3D Printing) equipment intensifies, and the number of shared spaces for making increases. Although it is possible to disseminate plans for objects to allow others to produce their own iterations without working collaboratively[22], Open Design also offers the possibility to develop artefacts as a genuine collaboration between makers. As Open Design is facilitated by the Internet and allows for a geographically diffuse set of participants, this presents the possibility of opening up the design process to people who are barred from traditional Participatory Design (such as those who are immunocompromised). Design can thus fit the Participatory model described above, and be brought to bear on Wicked Problems in a health context by engaging a wide variety of stakeholders in the process.

4.2. Open-Source Design

As already mentioned, open design is not a new idea. However, in assimilating the ideas from the 1970s, and the recent technological developments of the Internet and distributed digital manufacture, there is a need to define Open Design- to allow makers, designers, companies, users and indeed all stakeholders to know *when* to open the source for an artefact and *what* this should entail.

4.2.1. Manifestos and definitions

Open design is not simply a collection of convivial, physical and virtual tools- these enable the process, but open design necessarily require that the design activity happen in a particular way. Knowledge here is created through *making*- that is, by the creation and review of artefacts on an individual level or in a collaborative sense by a community. However, a designer does not have to develop their artefacts collaboratively for the design to be open source- Mari's furniture is open-source (albeit with an appeal for non-commercial production), yet not collaborative (Mari, 2002).

For Kadushin, one of the early exponents of open design, the prerequisites for an Open Design project is CAD data and its translation into a physical product by CNC machines (Kadushin, 2010). However, for Kadushin open design does not necessarily have to be collaborative.

[22] Enzo Mari published *Autoprogettazione?* In 1974, which documented a range of furniture designed for assembly with little to no prior knowledge of furniture making techniques. Mari invites makers of the furniture to send him photos of derivatives from his designs to his studio in Milan. More recently, Ronen Kadushin has been designing pieces of furniture with an expressly open-source methodology- disseminating the plans via the Internet for others to download and produce themselves.

(Katz, 2011) describes open design in the context of freedoms- specifically the "freedom to use the design, and the freedom to use it to make a derivative and use this for any purpose; the freedom to study the design and change it, and then change it to make it do as you wish"

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[23]:

> *"A piece of data or content is open if anyone is free to use, reuse, and redistribute it — subject only, at most, to the requirement to attribute and/or share-alike."*

Avital (2011) gives a summary of the features of open design (as distinct from open source and open innovation). The following table outlines Avital's summary:

	Open design is...	**Open design is not...**
Access	Available, shareable, licensed under open-access terms	Concealed, protected, licensed for a fee
Blueprints	Specified by common digital notation language	Specified by proprietary notation language
Derivatives	Reconfigurable and extensible	Black-boxed and fixed
Exclusivity	Reproducible	Limited to a finite series or a one-off
Means of Production	Fabricated by commercial, off-the-shelf, multi-purpose machines	Fabricated by artisan handiwork, custom-built machines or moulds
Manufacturing Process	Subject to distributed and scalable production	Subject to centrally controlled and preset batch production
Potential	Generative	Closed-ended

Figure 3- Table showing the facets of Open Design. Taken from The Generative Bedrock of Open Design, in Open Design Now (2011)

This process can be summarised in the following diagram, adapted from Atkinson's definition of the *Automake* process (2006):

[23] See more of the definition at: http://opendefinition.org

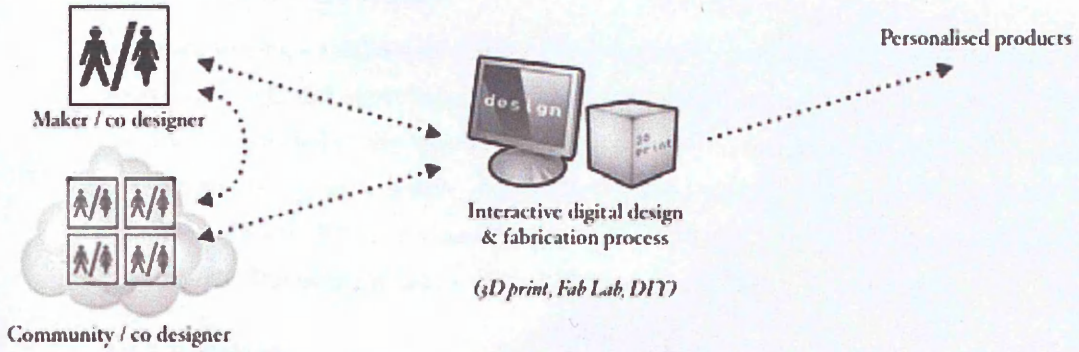

Figure 4 - Open Design diagram, adapted from Atkinson (2011)

The person wishing to make a product is able to engage in a collaborative design effort with other members of an online community. Of course, this is a collaborative vision for Open Design, rather than a linear process from designer to product, via maker as a proxy.

The whole community might be bounded by an entity or corporation, and focussed on a particular topic. Such a 'niche network' (Boyd & Ellison, 2007) might be directed after the style of an *Orchestra* (section 4.3.3, p52), with the development directed (to some extent) by the corporation. The 'Benevolent Dictator' of the open-source project is a good example here. Similarly, the community might be less tightly bounded by a particular topic or corporation- taking a much more general approach to the objects that are designed[24].

[24] Thingiverse.com is a good example of this. The site acts as a repository for a multitude of artefacts, with no specific theme beyond 'free to download CAD files'.

4.3. Open Innovation

Although sharing a similar name with open design, there are important distinctions between open innovation and open design. The biggest difference is the degree to which the design activity is conducted in the 'open'. It is entirely possible to conduct open innovation *without* the activity being open source. However, cited in the open innovation literature are examples of successful open source projects with Wikipedia, Linux and Apache mentioned prominently (Dahlander & Gann, 2010; Dahlander & Wallin, 2006; Gassmann, 2006).

4.3.1. Definition

The 'open' part of the term open innovation pertains to the external focus of attention for a company, in sourcing Research & Development (R&D) from outside of the corporation; this also affects the process by which the internal innovations of the company are treated. In the past, research projects that could not be internally commercialised were either licensed, or 'sat on the shelf' in the R&D department (Chesbrough & Crowther, 2006). Historically, the rise of the internal R&D department came about because of the economic benefits of sourcing innovation directly from within the corporation, rather than relying on the market to deliver this (Mowery, 1983). However, this internal development of 'shelved' ideas can be improperly implemented- A recent example that has been discussed in academic print (Chesbrough & Rosenbloom, 2002; Chesbrough, 2006), and popular culture in the movie *The Pirates of Silicone Valley* (Burke, 1999) centres on the research facility Xerox PARC (Xerox Palo Alto Research Centre) in the 1970s. Perhaps the most famous case of Xerox missing the opportunity to capitalise on the internal R&D produced at this centre was in allowing Apple Computer Inc. access to their Graphical User Interface prototypes; greatly speeding the development of Apple Computer's products.

From Dahlander & Gann (2010) we see that many papers from their systematic review of works investigating the idea of 'openness' cite user innovation, or open innovation literature. von Hippel (1986), and Chesbrough (2006) rank highly in their analysis of most cited works. In his work on lead users, von Hippel (1986) discusses the communities of people who modify equipment they use, and in doing so develop new products. This approach to using communities of people has been used in the development process for new product concepts, facilitated by the internet (Füller, Bartl, Ernst, & Mühlbacher, 2006).

4.3.2. Openness

In Open Innovation literature, there are 4 definitions of 'openness' (Dahlander & Gann, 2010) - although there is a recognition that the idea of being open is more of a continuum rather than a binary choice (ibid). These definitions are listed below:

	Inbound innovation	*Outbound innovation*
Pecuniary	Acquiring	Selling
Non-Pecuniary	Sourcing	Revealing

Figure 5 - Four different definitions of openness in innovation

Most interesting to the field of open design are the definitions of *Outbound Innovation*, since these can be used to categorise, or frame when an open source approach is most valid. Raymond (2001c) himself discusses criteria for open-sourcing a software project, and these in combination with Dahlander & Gann (2010) highlight that there appears to be a dearth of information about the disadvantages for working in an open way. In highlighting future research that is necessary, there appears to be a lack of evidence suggesting the costs of openness. For instance, in sharing the plans for an Open Design, there are immediate costs relating to the materials and processes by which the artefact will be produced (Raasch et al., 2009). This could be in the 3D printer filament, access to a community workshop, or even the outlay for purchasing Distributed Digital Manufacturing equipment.

There is also a cost associated to being 'open' in the sense that the search for other entities external to a corporation requires an investment in time, and also capital. This means there is the potential for 'over searching', which can have a detrimental effect on the innovative performance of an entity (Laursen & Salter, 2006). As the authors point out, this should give a more nuanced view of the term openness – rather than the utopian view put forward by Bowyer (2011), Anderson, (2010) and others.

4.3.3. Models and Organisation

In his chapter about crowdsourcing, (Press, 2011) cites the idea of Network-centric innovation (Nambisan & Sawhney, 2010). This *inbound* focus of the innovation effort for a company, includes the leveraging of different communities of actors:

> *'This approach reflects the essence of network-centricity – the emphasis on the network as the locus of innovation and the associated opportunity to extend, optimize, and/or enhance the value of a stand-alone entity or activity by making it more intelligent, adaptive, and personalized (ibid)'*

From their paper, *'The Orchestra'* is perhaps the most traditional of the organisation strategies, with a single actor acting as the controlling, directing focus. This approach is familiar with Linux distributors for example; Ubuntu being a good example, as Ubuntu is developed by the company Canonical Ltd, whose head Mark Shuttleworth goes by the title 'Self Appointed Benevolent Dictator For Life'. This references the idea posited by (Raymond, 2001b) that leaders of open source projects are necessarily dictatorial- however, benevolence is used to temper the necessary dictation of the work effort to avoid the project forking, due to a leadership battle[25]. This dictatorial approach governs the development effort of the interface for the Linux distribution Ubuntu (the specific appearance of this is referred to as Unity), and this description of the Orchestra as a metaphor for the guiding of the development process is apt, as it refers to the teamwork of specialist individuals, guided in their action by a conductor. Atkinson (2011) uses this same metaphor to describe Open Design, and the collaborative organisation of the design activity.

4.3.4. Open innovation in medical product design

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 in their daily self-management 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 Chesbrough & 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.

Similarly, Medtronic operate a web portal called EUreka, where medical personnel can submit ideas for consideration by Medtronic for possible future development. Medtronic

[25] The self-appointed title is a tongue-in-cheek reference to the title 'Benevolent Dictator', which is sometimes used to refer to those in the open source community who are looked upon as its leaders, or elders.

requires that the appropriate Intellectual Property protection has been applied *before* submission- this streamlines the process of adoption and internalisation of the idea. Both of these processes are *Inbound* Innovation, as they seek to deliver new sources of innovation *into* the company's development process. This is opposed to an *outbound* innovation approach, where either of these companies would seek to licence some intellectual property 'stuck on a shelf' in the internal research and development centre.

We can see from these two examples that while the products that are created from this process are more inclusive of the user and their experiences, the mechanisms for including the people who are affected by the products tend towards consultation, rather than collaboration (Arnstein, 1969; Carroll & Rosson, 2007; Müllert & Jungk, 1987; Spinuzzi, 2005).

4.4. Historical Context For Open Design

The methodology known as open design is not a new idea. During the British Industrial Revolution major advances were made in steam machinery, which revolutionised the process of pumping water out of mineshafts. In Cornwall, on the South coast of the United Kingdom the primary form of mining was for Tin. Initially, the steam engines for water extraction were 'closed source' - the plans hidden away behind the patents of litigious companies. Once these patents expired, the plans were dissected and shared amongst fellow engineers and companies via the journal Steam. This dissemination of ideas allowed for the rapid progression of iterative improvements to the steam pumps for mining enterprises, with the 'closed-source' engines struggling to keep pace, and eventually overtaken by the more advanced, and reliable open source competitors (Leadbeater, 2009; Nuvolari, 2004)

The writings of notable thinkers and environmentalists underpinned the foundation for the modern implementation of open design (Dexter & Jackson, 2013). Ivan Illich, E.F. Schumacher and Dennis Gabor all wrote in the 1970's about the need for a radical reinterpretation of modern manufacturing, consumption and societal organisation to stave off environmental and human decline. Illich (2001) wrote about the need for convivial tools for human use; that some tools and processes are dehumanizing when used, as they are simply *operated*, rather than used for fully satisfying, creative human endeavour. This approach typifies the modern attitude to mass production (Garrety & Badham, 2004; von Busch, 2012); with the individual specialisation of individual roles down to individual tasks on a continuously moving production line- the ultimate conclusion when treating humans as part of the wider system of production. Whereas Ilich writes about societal changes and the need for convivial tools, Schumacher (2011) writing in 1976, and Gabor (1972) also discuss the specific requirements of the tools needed for change.

These discussions are often rooted in the language of environmentalism- in that the imperative at the time was avoiding the apocalypse vividly portrayed by Jay Forrester's predictions from applying cybernetics to environmental models (Meadows, Meadows,

Randers, & Behrens III, 1972). Gabor discusses the issues society faces, and highlights 3 different priorities for the scientific and technologic community; those of the *avoidance of pollution, the avoidance of waste,* and *the technology of equilibrium* (Gabor, 1972). It is this use of the word equilibrium that ties the work to Schumacher (2011), and also Illich (2001)- for the use of science and technology to remove the 'zero-sum game with nature' (Gabor, 1972) whilst also advancing, or sustaining the living standard of the Human race. Most applicable to the discussion here is Gabor's call for the design and development of technologies that are easy to repair. Household items are mentioned by Gabor, who does not allude to the continuing miniaturisation of technology to its current state. Miniaturisation of technology is used as an excuse by companies for producing devices that are difficult or impossible to repair[26] – however there are companies producing high-tech products that are open to repairing the different components. Teenage Engineering have made use of bespoke digital manufacturing services such as Shapeways to fulfil individual requests of their consumers for replacement parts for their synthesisers (Shapeways, 2012), and Fairphone are publishing the internal specification of their smartphones on ifixit.com; allowing the user to become a DIY smartphone technician[27]. These applications prolong the life of the devices, which as Gabor notes would cause the waste of rare-earth, and exotic materials.

4.4.1. The Requirements of Technology

In Schumacher's case he writes about the requirements of technology and scientific advancement in relation to humanity's needs. Schumacher notes that humanity requires technology that is (Schumacher, 2011 p 21):

- Cheap enough so that they are accessible to virtually everyone;
- Suitable for small-scale application; and
- Compatible with man's need for creativity

Schumacher also writes about the need for radically altering the model for production and consumption of goods and services from this linear 'take make waste' (mass production, consumption, waste) to sourcing materials, labour and services at a local level for local production and consumption that would fit the requirements of the communities they serve more appropriately. Also, this model would facilitate the creation of a 'cyclic' model of consumption, where the product is recycled into its constituent parts for energy, or integration into other artefacts at a local level. Writing in the mid 1970's however, Schumacher, Illich and Gabor could not have foreseen the impact that the Internet would have on the whole of human society, or the potential that this technology has to facilitate the models they proposed in the 20th century.

[26] As an example, the latest notebook computers from Apple scored very poorly in the popular self-repair website ifixit.com review, with components (usually user-serviceable, like RAM) soldered to the main logic board, and batteries glued to the notebook housing. These choices are made to produce a thin notebook, but they have an exceedingly detrimental impact on the ability of the user to service, or even upgrade the computer.

[27] See http://www.ifixit.com/Device/Fairphone for more information. Fairphone handsets come preinstalled with the ifixit.com app.

The current tools and places for open design build on the ideas described by these 1970's thinkers (Dexter & Jackson, 2013). For instance Distributed Digital Manufacture in community spaces allows for the production of artefacts by amateur designers in a way that was not possible for the vast majority of people until recently. The open-ended nature of these tools mean that they can be used for work that is fully satisfying (in Illich's terms), whilst also fulfilling the criteria set out by Schumacher in that they are 'cheap'- insofar as the cost for a 3D printer has plummeted since Adrian Bowyer published his paper on the RepRap project (Jones et al., 2011). The machines themselves are very suitable for small-scale application, since most of the domestic 3D printing scene consists of open-source 3D printers (Moilanen & Vadén, 2013), which have freely available plans that anyone may download and build. A person can operate these machines wherever power and filament can be obtained.

The political philosophies of the movement find an overlap with the democratic, emancipatory underpinnings of the participatory design movement (Kensing & Blomberg, 1998).

The democratisation of production, or some of the advanced tools for production is happening. This allows for consumers of products to become collaborators in the design, and the manufacturers of artefacts. The open-ended nature of these tools fits the call for creativity required by Illich; the low cost, increasing availability, and creative use answers the requirements of Schumacher; the ability to aid repairs, and to produce and recycle artefacts instead of consume and discard mean that Open Design is a step towards the future that Gabor imagined.

The distributed nature of the production activity, facilitated via the Internet and utilising machinery that enables increasingly complex and refined parts to be produced has lowered, and is lowering still the barrier to production. This Distributed Digital Manufacture is more informal than the Internet-enabled distribution between traditional factories and industrial partners (Mahesh, Ong, Nee, Fuh, & Zhang, 2007; Mahesh, Ong, & Nee, 2007), instead utilising the informal networks of designers and makers found in the Fab Lab network, or a sharing platform like Thingiverse.com.

4.5. Spaces

The evolution of spaces that the modern maker movement, and with it the manifestos and foundations for open design have been formed from different directions. These different approaches share egalitarian aims, differ in their direction. Troxler (2011) gives a library of different peer production methods, which he describes in terms of tending towards more generative design and production work, or whether these are instead focussed more towards production. Indeed, the different spaces currently allied to the production of open source artefacts might seem initially subtle in their differences, yet each have developed from different actors, and different circumstances. Some initiatives aim to make distributed digital production available to the widest possible audience, and others aim to give makers the opportunity to create something new; the difference between reimagining the factory (as in the first case), or reimagining the design studio (second case).

Reimagining the factory will make a direct link to the historic writings from the 1970s, and the ecological / sustainability arguments for reimagined methods of production. The community design / production studio has a strong link to the participatory design community in it's egalitarian and democratic philosophy.

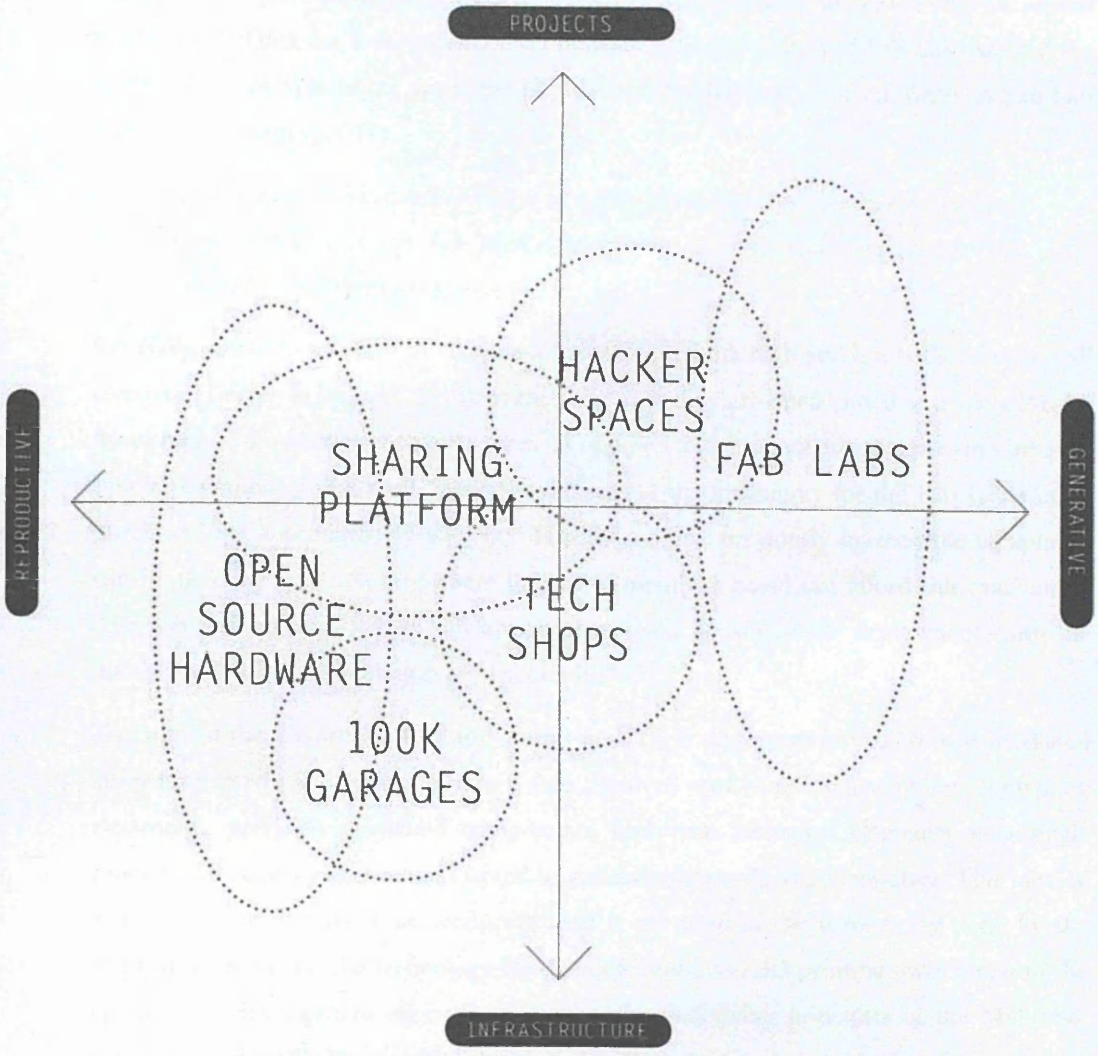

Figure 6 - Libraries of Peer Production (Troxler, 2011)

Troxler's Libraries of peer production provide a good overview of the current physical / digital spaces that facilitate the open design (and production) of artefacts. These spaces deal with the physical aspect of making- since open design is about the 'collaborative creation of artefacts' (Atkinson, 2011) then there comes a point at which the digital CAD file becomes tangible. There are entirely virtual spaces for collaborating in the design process (or sharing creations) that act in addition to this list.

4.5.1. Fab Labs

While the rise of the hobbyist 3D-Printing movement has led to many proclamations of the next industrial revolution, there are important factors beyond 3D printing that must be taken into account. For instance, Microwave Ovens were touted as being 'the future of home cooking' (Gershenfeld, 2012) at the beginning of their introduction in the 1980's (ibid)- yet traditional cooking methods still abound. Similarly, this has led to those involved in the field to proclaim that 'the revolution will not be 3d printed, but it will be fabricated. Digitally.'

(Jackson, 2013). In an article for Foreign Affairs, Neil Gershenfeld (2012) talks in similar terms, highlighting the locally-sourced yet globally managed system of Fab Labs around the globe. Fab Labs were borne out of the MIT Centre for Bits and Atoms (CBA)[28]. A Fab Lab consists of (Charney, 2011):

> *"A Fab Lab (Fabrication Laboratory) is a fully kitted fabrication workshop which gives everyone in the community, from small children through to entrepreneurs and businesses, the capability to turn their ideas and concepts into reality."*

Crucially, the tools involved in creating a Fab Lab are both high and low tech. They are all convivial (Dexter & Jackson, 2013), in the sense that they are open ended and allow for the flourishing of the person who works them (as opposed to dehumanizing that person's input to simple operation of that tool). Similarly, the sum of the machinery for the Fab Lab can be purchased for approximately $50,000. This means that previously inaccessible equipment can be used by a community where individual members could not afford this machinery. The convivial tools of a Fab Lab are cheap enough for wide-scale deployment; with the number of Fab Labs doubling every 18 months.

The aim of the Centre for Bits and Atoms at MIT is that eventually there will be digital fabrication methods that can produce fully resolved and complex assemblies (containing electronics, precision machined components, and even biological elements) as a single process; even that these machines would be capable of reproducing themselves. This ideal of a machine that is capable of producing itself is mirrored in the work being done by the RepRap community; the technology for domestic (hobbyist) 3D printing owes much to the open-source development effort. For instance, the underlying principles of the MakerBot company, and the Utilimaker 3D printers is of a direct consequence of the RepRap project.

The Fab Lab model from MIT also encourages peer-to-peer learning and the education of children in a distributed fashion. This 'Fab Academy' is a way of children learning different skills at a local level, but with global knowledge and tutelage. This egalitarian outlook has meant that Fab Labs have become synonymous with the development of the open design movement (Menchenelli, 2012).

[28] http://cba.mit.edu/

Figure 7- The Amsterdam Fab Lab

Of course, there are those who wish to see the Fab Lab model developed further, to be an engine to drive economic growth in countries with a history of producing, but with stalled (or dwindling) manufacturing sectors. For example, Pelling (2011) makes the case for including industry-standard manufacturing equipment in the Fab Lab:

> *"A serious attempt at seeding manufacturing would have proper kit for startups who are driven to change the world, one good idea at a time: an EOS direct metal laser-sintering system, a 3-axis computer controlled mill, a decent laser cutter, and so forth"*

4.5.2. Hackerspaces

According to Pettis and Astera (2009), a hackerspace is a place where:

> *hackers gather to solder electronics, share programming skills, teach classes, and build a community of intelligent, inquisitive, and clever people.*

Unlike the Fab Lab, there is not necessarily a focus on production of physical artefacts. Instead, the mix of physical and digital artefact modification or creation depends upon the hackerspace, and the community of hackers[29] that make it up.

[29] Richard Stallman, the creator of the Free Software Foundation and one of the early pioneers of modern computer programming describes a Hacker as: '*...someone who enjoys playful cleverness, especially in programming but other media are also possible' (2002).* Some early Hackers used their programming ability to circumvent security on networks, or computer software. The Hacker culture 'never had much respect for bureaucratic systems' (ibid), and while not every Hacker broke security or had an interest in doing so, the name became synonymous with deviant behaviour.

The counterculture movement that developed from the liberal thinking in the 1960s and 1970s became the background for the rise of hackerspaces (Grenzfurthner & Schneider, 2009). This accounts for the organising principles and their ontological makeup; the Grenzfurthner & Schneider recognise the failure of the commune's in their essay, but they apply this to the politically motivated squats of empty housing. Curtis (2011) goes further in critiquing the idea of the totally flat community, and while organisation and resourcing might be a collective activity, membership fees and structure are often used to bind and sustain the hackerspace. This should not be seen as a criticism of the movement, rather the recognition that a 'more flat' community of users is possible. However, roughly half of all registered hackerspaces are dormant (Troxler, 2011).

Both Fab Labs and hackerspaces have little to no 'top-down' organization, and often have Grassroots beginnings (especially true of the hackerspaces). However, the focus of making physical artefacts defines the Fab Lab; hackerspaces do not share this focus on the 'physical', but do not eschew people pursuing these projects.

These two examples are not the only forms of community 'making' (or even 'community making') collaborations; the 'Lab' suffix is not a protected entity by MIT, meaning that the growth of other spaces outside of the Fab Lab community happens naturally. Similarly, there is no mandated path by which a hackerspace becomes established.

A significant number of hackerspaces originated in Germany, with the oldest originating in a pre-unification Berlin[30]. These spaces, whether in Germany or the rest of the world have a strong emphasis on the commons- the free-to-access nature of the spaces (with the recognition that there are sometimes members-only meetings, or private functions) means that they are often engaged in political activism and social justice issues, as well as coding and electronics (Pettis & Astera, 2009). The democratic, decentralised nature of these groups harks back to the writings of the 1970s mentioned earlier in this chapter, and are a natural fit with the methodology of open design. Membership might not be formal either, with casual users and those who infrequently attend the space being integral for the flourishing of the community (Farr, 2009).

A common strand between these two spaces is the learning or tuition involved. This has been formalised to an extent by the 'Fab Academy'- the means by which skills are transferred between Fab Labs via broadband video sessions (Charney, 2011). Similarly, in a Hackerspace, informal tuition and group based-problem solving are common (Pettis & Astera, 2009).

The term Hacker has been applied to other areas since the turn of the century, although predominantly linked to the open source software community. There are parallels to this in the modern open design and maker movement, with websites like *IkeaHackers.net* a community of people who alter Ikea furniture to solve bespoke requirements, or form artworks.

[30] The *Chaos Computer Club Berlin* began life in Hamburg in the eighties, and though it has moved premises a number of times, it still operates today.

4.5.3. Production / Infrastructure

100K Garages and TechShop both employ subtly different models in their implementation, but both are examples of spaces that lower the barrier to entry for people to produce their own artefacts. Crucially, these initiatives differ from virtual production methods (like Ponoko, Shapeways or even virtual communities such as Thingiverse.com) in that they allow for communities of people to access the means of production in ways that meet Schumacher's 3 criteria.

TechShop began with the opening of the first workshop in Menlo Park, California on October the 1st 2006 (Boyce, 2006). Currently, there are 6 TechShop workshops in the United States of America[31], which are supported by a monthly membership fee[32]. However, these are not spaces that are free at the point of access for the public, and with no commitment to share the plans that are created. This is not to say that TechShop workshops have not provided an invaluable space for fledgling business ideas, with prototypes produced for startup companies and also third-sector organisations (Rivlin, 2011). As a service offering, the individual Maker can access in TechShop a range of production methods that would be beyond most DIYers.

100K Garages was started by the company ShopBot, who manufacture CNC[33] tools as an extension of their already popular community forum on the ShopBot website (aimed at pairing makers with people who had access to ShopBot CNC machine tools). ShopBot paired with Ponoko, a distributed manufacturing platform (with the ability to digitally manufacture in New Zealand, the USA and Europe) that launched a laser-cutting service and software platform in 2007. 100K Garages acts as an intermediary for people who wish to produce something, and producers looking for a way to utilise their own machines. For instance, if a person wishes to produce an artefact, they can use 100K Garages to find a producer, who will then take their digital plans and manufacture, pack and ship the artefact.

4.5.4. Sharing Platforms

A key feature and benefit of Open Design is that it is facilitated by the internet- allowing for collaboration or dissemination across territories, and with many disparate actors. This sharing requires spaces in which to facilitate design activity, to allow for conversations around the blueprints of these artefacts to develop. Some spaces encourage the use of prototyping facilities by the site owners, and some sites exist more to allow for the dissemination of 3D artefacts to a wider community.

Shapeways and Ponoko are both platforms that allow makers access to digital fabrication technology in the form of a bureau service; users can upload designs and have them

[31] http://www.techshop.ws/locations.html
[32] This fee is approximately $100 USD per month. This includes access to the industrial machinery of the TechShop, which is worth many hundreds of thousands of dollars. There is also access to the skills and advice of the technicians via classes and demonstrations; whilst also including free coffee and popcorn.
[33] CNC stands for Computer Numerically Controlled. These machines can be used for distributed digital manufacture (usually Subtractive manufacture), and have been used for the Rapid Prototyping of ideas.

produced and shipped back to them. However, both have marketplaces where the makers can have their designs for sale on the Shapeways or Ponoko sites. Both producers differ in their approach, with Ponoko offering a more complex assembly package (both electronics and materials can be assembled), while Shapeways has focussed instead on offering a large range of professional-quality material options. For instance, Shapeways can offer production in Gold-plated Bronze, glazed Ceramics, Sterling Silver, and a range of different plastic grades[34]. In 2012 Shapeways produced and shipped their 1 millionth artefact (Smith, 2012), and Peter Weijmarshausen, the CEO of Shapeways, comments on 3D printing- suggesting that users prototype at home using their 3D printers, and then use Shapeways to produce in a higher-quality material once they are happy with their design (ibid).

Thingiverse.com is owned by the MakerBot corporation, and was set up in 2008 by Bre Pettis and Zach Smith as a repository and community space for makers who wanted to share their 3D creations. Users of the Thingiverse site upload CAD data pertaining to a number of different digital manufacturing methods (laser cutting, 3D printing, CNC machining, etc.) that is tagged and catalogued by the Thingiverse.com site. This information is indexed and searchable – meaning that a maker can search for designs similar to their own from which to draw inspiration, or to derive a completely new artefact. The designer applies a license which dictates the uses permitted by others for that design.

These interactions might be relatively simple in nature, or they might be in-depth discussions that reach into the ethical implications of the objects themselves[35]. Thingiverse.com differs from Shapeways and Ponoko in a fundamental manner- ideologically Thingiverse.com is built on a foundation of openness and freedom; users of the site cannot charge money for the plans they create[36], and they are not able to have them manufactured by Thingiverse.com (or the MakerBot company). The open and reciprocal nature of the terms that objects are uploaded to Thingiverse.com has meant that the community has grown rapidly, with MakerBot recently celebrating the 100,000th user-generated artefact to be uploaded (Jhoward, 2013).

3D Systems released a product service offering similar to the implementation that MakerBot chose for their Thingiverse.com site; as in, they have released a hardware and software platform for producing 3D prints. Their Cubify printer is marketed as a simple, easy-to-use 3D printer. Their software platform allows for the sharing of 3D files, but as the software requires the designer to charge for their designs, this functions much more as a marketplace for these designs than a site for sharing or collaboration. Not all people were convinced by 3D system's introduction of the Cubify printer, even as it won accolades from The Washington Post and c|net.com. Sinclair (2012) pointed out that the Cubify from 3D systems (a giant in the industrial 3D printing space) seemed more focussed on monetising the

[34] This assumes that the CAD model generated by the maker has the appropriate properties, such as wall thickness, tolerances for mechanical parts, and physical dimensions (not too small, or too large).
[35] This was a feature of the conversations that I had through using the Thingiverse.com site to disseminate the plans from the collaborative design work in the case study that made up this PhD research. See Appendix A, p 76.
[36] At the time of writing this was the case. However, after the PhD viva Thingiverse.com allowed for the paid download of certain CAD files.

process of file sharing, printing and owning the Cubify. For instance, the Cubify printer(s) use proprietary filament packs, instead of the bulk plastic filament that their competitors use. There are hacks for the Cubify, to allow for generic plastic to be used (Szczys, 2013), but tellingly on the Cubify website there is no way of researching the price of the consumables for the printer, or assessing the cost of ownership prior to purchase.

4.6. Free / Libre Open Source Software

It would be remiss of any discussion surrounding open source development to not include some analysis of the origin and impact of open source software development. A key text in this discussion is Raymond's (1999) documentation of his development of an open-source email client. However, we all feel the impact of open source software, even if we do not recognise or have the eye to acknowledge it. Linux is the foundation to innumerable Internet services, and even the most popular Smartphone operating system on the planet. Similarly, Microsoft's development of Internet Explorer after version 6 became frustrated by the development of the open-source web browser Firefox (of the Mozilla corporation).

Raymond (2001b) and Troxler (2011) suggest that a fundamental error in some people's logic is to compare computer code with a traditional manufactured good. In this respect, the logical fallacy is to assume that no products with accessible source code could be commercially successful, since the code could (theoretically) be copied and *internalised* (see section 4.3.2, p51) by another entity. These concerns have not stopped Red Hat, and others from becoming successful software companies (Red Hat was the first open-source software firm be included in Standard & Poor's 500 index[37]).

However, what about comparing code to a non-traditional manufactured good? Digital Distributed Manufacturing does not follow the conventional method for mass production. There are similarities to some of the cutting-edge applications of mass customisation in allowing for the 'consumer' to create their own artefacts to augment a purchase. However, Distributed Digital Manufacturing could be used by companies to allow for diffuse production (perhaps in community spaces not formally part of their supply/manufacturing lines) which could follow similar patterns of development to open source software (Raasch et al., 2009); bug-checking, documentation, incremental evolution would all play a part in this distributed model of manufacture- providing it was conducted in an overarching open-source methodology (Open Design).

However, we should be wary of drawing an indelible connection between the two approaches. In Raymond's (1999) closing remarks of his collected works around *The Cathedral and the Bazaar*, he highlights the fact that certain creative works do not need to be debugged; a requirement that in Raymond's opinion does away with the need for peer-review, and therefore the benefit of open sourcing the project. This view does not preclude the

[37] This was reported in Slashdot in 2009. The Standard & Poor 500 index is a list of the top performing 500 companies in the United State of America. Red Hat has had annual revenues exceeding $1 Billion every year since 2011. (http://linux.slashdot.org/story/09/07/18/1327248/Red-Hat-Is-Now-Part-of-the-SampP-500)

application of these approaches, but it should temper the desire to view open source design as a utopia- a broad brush to fix all of the problems associated with traditional manufacturing; rather than an opportunity to find a hybrid, middle ground.

4.6.1. The problem of continuous peer-review

As mentioned previously, Raymond (1999) is cautious of the over-application of the term 'open source' to creative endeavours outside of software development. One of the main points that Raymond cites is the absence of the need for continuous peer-review of development for books, and music (examples). However, the betterment, or honing of a particular piece of code to resemble poetry (Coding as a craft is explored by Sennett (2009)[38]) is perhaps analogous to the remixing and adaptation of the artefact by others into different situations. Raymond talks about embedded software, and how the code for a specific application is not easily appropriated by others (Raymond, 2001c) for use in their own situation.

As an example, certain Computer-Aided Design (CAD) files that are produced for dissemination by people working with open design are *parametric*. For example, the CAD file has user-modifiable variables (e.g. the geometry of a part). A good example would be a CAD file for a gear; in an immutable CAD file, the numbers of teeth (and the other aspects) are fixed, but with a parametric file another user could change the number of teeth, (or diameter of the gear, etc.) to fit their own application. This is easier than drawing the part from scratch, and as such the fact that a part is 'parametric' is prominently advertised when shared on a site such as Thingiverse.com.

Taking a parametric view of the artefact (e.g., and artefact that is not difficult to modify) challenges the analogy with embedded software, since debugging hardware is no longer the sole focus, but remixing and iterative development of the artefact. Thus the process of designing an artefact is analogous to the bazaar, with multiple individual designers (rather than coders) remixing, collaborating and adapting physical artefacts ad infinitum (or until a particular strand of development runs its course).

This is not to say that 'debugging' digitally created artefacts is not necessary; complicated artefacts require debugging just as beta software does. Designing an artefact with interlocking or moving pieces means that different tolerances are required, and printing in different materials and with different processes will mean that different tolerances will need to be tested- having an impact on the design (and therefore of the CAD file)[39].

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[38] Sennett also highlights the etymology of the word *Poetry*, highlighting that it's parent word is the ancient Green 'Poiein' – to make.

[39] For instance, Thingiverse user 'Emmett' published a CAD file for a model representing an automatic transmission[39] on the 12th of November 2012. This artefact is very popular (at the time of writing, it has been downloaded 50,981 times), on account of it's complexity, and scale. By Emmett's own admission, successful printing of the artefact requires a machine in tip-top condition, with the tolerances being so fine for the moving parts, even being affected by the degree of shrinkage for the printing material. The initial comments on this posting complained of the difficulty in obtaining a successfully working mechanism (as the author can attest), as the tolerances on a particular part were so fine. 7 days after Emmett's initial post, 'SystemsGuy' posted a reworked part with increased tolerances[39]. This derivation of ideas appears analogous to the debugging effort mentioned by Raymond.

The logging and communication of this effort is important, and just as there is a requirement for open source software to be fastidiously documented, there exists a similar need for 3D artefacts. The communication medium of this information is still under investigation – how might an amateur designer communicate the learning behind the successful production of an artefact? There are many variables (all of which need to be documented, so they can be 'debugged'), from the environmental, through to technical, and even down to the tacit knowledge of the maker.

This production of knowledge and its subsequent incarceration in the tacit realm within the maker is similar to the production of knowledge described by Sennett (2009) for medieval craftsmen. For instance, while an initial comparison of a carpenter to a modern day maker might appear crass, both create knowledge in the act of making; perfecting this knowledge to the point that they rise above the minutia of the skills used, and can self-reflect on their process. The work both undertake is fulfilling too- consider the medieval carpenters pursuit of the best table that could be made, and the modern day equivalent of the maker producing complex, intricate designs, often in their own spare time. These are not the demoralised workers Sennett describes in the former Soviet Union; rather these are people who conform to the Illich/Schumacher ideal of doing work that is fully satisfying for humans, whilst also obeying the three requirements laid out by Schumacher for the technology involved in the process.

4.7. Hierarchies, and organization of open source development

Decentralised, diffuse and internet-enabled collaborations of the scale of modern Linux development appear 'flat'; or, that they do away with traditional hierarchies and allow for a truly self-organising system. This assumption is false- open source software development is directed, with new programmers (hackers) joining a project and proving themselves by not just patching code, but by writing documentation and debugging. A programmer contributes their time, and their skill- in turn building a reputation and a standing in the community. Other members of the 'hacker' community confer the label 'hacker' on that programmer once they have proved themselves able to understand the culture, and correctly apply the customs of the hacking community - one cannot apply the label by themselves, unchallenged (Raymond, 2001b).

In his documentary from 2011, Curtis critiques the notion of 'flat' communities by highlighting the pioneering communes of the 1970s, and the fact that these failed due to a lack of control over any individual's power over another; there were no formal 'checks and balances', since any person requesting aid against another actor's influence was taken to be building a coalition (Curtis, 2011). Instead, the Linux community is more akin to a guild, or of a medieval craft tradition (Raymond, 2001a; Sennett, 2009).

4.7.1. The Revolutionary Internet?

Open Design, and open source approaches more broadly can be seen as an ideological position- a position to defend in the same way as one might defend the right to free speech- or indeed, a democratic government. Richard Stallman's Free Software Foundation aimed to do just that ('Free' as in freedom, not free as in 'Free beer'). Some prominent proponents of open source development paint a utopian view of this method for production of code, or physical artefacts. Adrian Bowyer (2011) provocatively suggests that if human beings can produce any material object we require, such as a pair of shoes, is the concept of money void? The RepRap project is an exercise in developing machines that can copy themselves, creating generations of machines by consuming power and raw material. Gershenfeld (2012) discusses the different materials that could be used to produce such systems; materials that could be disassembled back to their constituent parts and rebuilt into another configuration. The example used is that of Lego, the construction toy. Gershenfeld compares Lego to current 3D printing, showing that Lego as a Digital material, is not prone to errors as the construction process happens, can grow out from it's origin and is bound only by the number of available parts (rather than a build platform of a 3D printer), and that Lego pieces of different materials can be combined. Finally, Gershenfeld makes the connection between Lego as a digital construction material, and ribosome- the 'protein that makes other protein [sic]' (ibid, 2012).

The Internet has been frequently used to promote the idea that the free access to communication media (such as twitter) can facilitate a spontaneous, leaderless uprising against authoritarian or ineffectual governments. This has been postulated in positive, and negative ways; the London riots of 2011 were facilitated by internet enabled communication tools, such as Facebook, Twitter, and BlackBerry Messenger – the latter proving the most difficult to trace because of the use of arbitrary 'BBM PIN' (Personal Identification Number) handles, rather than the accounts being linked to personal information in such a direct way as other social media tools (Baker, 2012). These riots, and the use of the communication tools to self-organize and direct looting or mobs resulted in prominent discussions about censorship, and the government's authority to limit access to the Internet in extreme situations (Baker, 2012; England, 2012; Fuchs, 2012; Tonkin, Pfeiffer, & Tourte, 2012).

However, the use of such social communication to facilitate the distributed organization of a large group of people has been seen as a positive contribution to the uprisings against authoritarian Arabian governments – known as the 'Arab Spring'. The use of Facebook, and Twitter, has been suggested to have had a great impact on the efficacy of the groups involved. The uprisings were apparently facilitated in no small part by the communication tools used by the protesters.

However, Curtis (2011) has cast doubt on the ability of technology to facilitate such 'leaderless revolutions'- citing the 'Orange Revolution' and it's initial success in leveraging new technologies to challenge the rigged election of Viktor Yanukovych. This revolution has

been dubbed the 'first Internet-organized mass protest' (McFaul, 2005), with people using mobile phones to organize and direct their protests (Goldstein, 2007; Kalil, 2009). Curtis is sceptical about the creation of self-organising communities facilitated via the utopian view that the internet allows for flat, leaderless activity. Indeed, Curtis is not the only dissenting voice. Indeed, there is little evidence that Twitter played a pivotal role in the organisation of the 2011 London Riots (Baker, 2012).

Morozov (2012) critiques the widely held belief that the internet-enabled communication tools used in the Arab Spring were as influential as they have been billed. Morozov uses the analogy of the photocopier, and it's perceived influence in the fall of the USSR at the end of the Cold War. The photocopier was used as a means of producing contraband publications spreading western democratic values, and although cited by prominent western figures as being a major factor in the fall of the USSR Morozov calls this influence into question, as citizens of the DDR had access to Western satellite media (the state turned a 'blind eye'), and yet the populace failed to become revolutionary against the state.

It seems appropriate to remember the strong critiques of the utopian view of the impact the Internet has made in democracy and society when approaching similar utopian views about open design. Indeed, Cruickshank & Atkinson (2013) take a sober look at some of the claims of open design proponents, asking what scenarios are best approached with an open design methodology. It is worth remembering that Eric Raymond, a historian of the open source software movement provides criteria for selecting when a coding project should be open or closed source (Raymond, 2001c). This pragmatic view of open source, and the desire to make an economic, engineering argument for its implementation apart from the ideological foundation that it has, means that this causes friction with those who think that the project should be open source *purely* for these ideological reasons; rather than justifying the use based on pragmatic economic criteria.

4.8. Open Design Controversies

Open design is a contentious issue, even amongst those who practice as designers / makers / community leaders, do not always agree on doctrine and procedure. This is especially true for those for whom open design presents a disruptive influence on the status quo. Allowing the 'consumer' of a product access to the means to develop and change that product (even going as far as to use the product for a totally different function) flies in the face of received wisdom that assumes total control is the best, and indeed only, way of successfully doing business (Laursen & Salter, 2006).

4.8.1. Intellectual Property

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).

During the 2011 Power of Making symposium, Pettis (2011) announced that people (and corporations) must 'Share or Die'.

> *'If you don't share, someone else will share for you.' (ibid).*

One of the staunchest early supporters of sharing the blueprints to one's own work was the MakerBot 3D printer company's CEO Bre Pettis. Former business associates have questioned this position, along with other community members since MakerBot declined to make the latest iterations of its 3D printers open source at launch.

This idea of sharing, or having one's IP 'shared for you' if a great concern at the moment, since the current system of intellectual property and copyright seems to be at odds with the idea of freely-distributed ideas & plans. Pettis and Bowyer[40] are idealists- both stated at the Power of Making symposium that theirs is a utopian view of a society free from the constraints of capitalism, where people manufacture their own products.

While current domestic 3D printers might not be as sophisticated as industrial equipment, there are already a large number of people creating and sharing their digital plans and ideas on the Internet. Standard copyright legislation recognizes 2 states for a work- All Rights Reserved, or Public Domain. These are self-explanatory; All Rights Reserved means that the creator has indicated that the right to copy, modify, derive and sell remains exclusive to them- until the copyright expires (this varies depending on the type of work, and in which territory it was produced). Once the copyright has expired, then the work exists in the Public Domain. This state allows any person to use the work in any way they see fit. A person may create an artefact, and then immediately release this into the Public Domain, ceding all

[40] Inventor of the RepRap open-source, self replicating 3D printer

rights. This status quo does not facilitate the emergent culture of remixing, mash-ups and collaborative, internet-centric working.

4.8.2. CopyLeft

CopyLeft is a play on the name Copyright, and was created by the *Free Software Foundation* as a way of referring to the rights attributed in the GNU General Public License[41]. The GPL is 'anti-business' (Pearson, 2000), as the licence requires that any derivative of *Free* code must itself be free, with no opportunity for becoming part of a proprietary system. This ideological stance is what has driven the development of the open source initiative, as open source software licences do not necessarily make such a distinction for derivatives (and can therefore be integrated into corporate software practices). However, there are a very wide variety of licences used in open source and *Free* software. It would be a mistake to lump the two categories of licence into binary definitions of 'fully' open (GPL) or 'hybrid' open (BSD[42]). There are a myriad of different licences that a coder can choose from, that all afford subtly different rights of distribution, derivation, and so forth for coders.

4.8.3. Creative Commons

Creative Commons licenses offer a 'some rights reserved' approach, allowing for a creator to release an artefact to a wider community, but controlling what permissions are set for that piece. This approach seeks to ensure that the creator retains authorship and credit, whilst also allowing for greater dissemination than traditional copyright.

Users select a Creative Commons (CC) license that is applied to their file(s). This license outlines the permissions granted by the author, above and beyond the statutory Copyright legislation. The licenses themselves are overseen by the Creative Commons foundation, a non-profit organization concerned with overseeing the CC standard.

The foundation of the CC license is the legal text, which is based on existing copyright. This forms the backbone of the license. However, this legalese is incomprehensible to most of the general public. Hence the use of the second layer, which translates the permissions laid down in the legal framework into plain English (the Commons Deed). This translation can be viewed online at the CC website, via a clickable icon that can be embedded on the web page containing the artefact requiring protection. It should be recognised that this is *not* in fact legally binding text, and it does not appear in the legalese. The final layer is entirely machine readable, and applied to certain types of files (for example, sound files, pictures, etc.) that interact with compatible editing programs.

Traditional copyright and IP laws have come under intense scrutiny from policymakers in recent years, since there is a growing sense that they do not work well in a 'Web 2.0' user-generated content Internet. Kroes (2011) argues that the current copyright infrastructure is

[41] See more at the 'What is Copyleft?' page at the GNU website: http://www.gnu.org/copyleft/

[42] The 'Berkeley Software Distribution Licence'. It is a 'permissive' open source licence, because it does not require that subsequent derivatives be released under the same licence as the original software. This means a derivative could be folded into proprietary software. All *Free* licences are open source, but not all open source licences are *Free*.

'not succeeding in its objectives'. Kroes argues that copyright should be a tool to recognize and reward artists, but often is used as a way of punishing and withholding information.

4.8.4. Professional Identity

For some practitioners, handing over the tools to enable a non-professional to design an object of their own volition is problematic. When the researcher delivers lectures on this topic to undergraduate students, there is often debate afterward around this notion- practitioners identify with their trade (Sennett, 2009). Open design and the democratisation of production methods is not the first instance of professional tools becoming part of the mainstream. Other creative industries faced the same issues- a good example is the development of accessible Desktop Publishing (DTP) software / hardware in the 1980's (Bowman & Renshaw, 1989). The development of the hardware and software for WYSIWYG development of print media meant that lay users now found they could visualise and produce their own media. Bowman & Renshaw use the term *Lasercrud* – the production of poor quality work made possible by the new technology at a lay user's disposal.

The democratisation of a production method can mean that items of dubious quality are produced. The authors quote Tilden (1987) discussing the impact on the rapid acceleration of the design process that DTP allows, and the resulting 'rush to print syndrome' that affects the quality of the output. This is a symptom of the haste in the process, which discards steps such as proofreading.

In incorporating these designs into their own derivations, the designers themselves need to be assured of the quality of these designs. Downloading and testing the designs could achieve this, but with ever-increasing complexity in the parts produced, this might not be feasible. The British Standards Institute produces documents that standardise certain design or production techniques to ensure quality, yet with the distributed development of artefacts by multiple collaborators (or designers producing derivatives) the current system of expensive and esoteric documentation is inappropriate (Dexter, Phillips, Atkinson & Baurley 2013).

Of course, this does not mean that good design is not possible by amateurs, and such a paternalistic view of the profession of design is at odds with the democratic view of Participatory Design; also the acknowledgement of the requirement for multidisciplinary working, and the increasing voice of the users is at odds with the notion of the professional designer being the sole vanguard of taste and source of well designed products.

Bowman & Renshaw (1989) conclude that firms seeking to lessen the output of *Lasercrud* could employ professional designers to train staff about kerning, white space and font choice- the modern equivalent of Massively Open Online Courses (MOOCs), YouTube tuition videos, or subscription based tuition sites like Lynda.com or TreeHouse.com.

It is possible to see *Lasercrud* equivalents in the 3D printing paradigm. However, as the quote from Bowman & Renshaw (1989) below highlights, the modern discussions around the

design of tangible objects is not so different from the discussions around the introduction of DTP:

> *By now virtually everyone has heard the term, 'desk top publishing' which is the current buzzword for producing documents with almost type set quality using equipment that can sit on a desktop. While the term is a misnomer - the equipment does not really publish desktops, nor does it actually 'publish' from a desktop…*

The democratization of the methods of producing high-quality artefacts and collaborating with a multitude of other designers (lay or professional) exists. The improvements in the means of production and communication promise to reduce the barriers to participation further, and broaden the scope of productible artefacts.

(Keen, 2007) wrote his polemic about how the Internet, and specifically the 'Web 2.0' technologies that enable and drive user-driven content are killing traditional creative professions, which links back to the outmoded view epitomized by the quote earlier from Paul Rand. The role of the (product) designer has been shown to be changing. Valtonen (2007) identifies that the product designer is now no longer restricted to form, function and production, but the intangible aspect of service & experience design. One could go further and suggests that the role of the designer will become more one of facilitation, becoming more of a 'meta designer' designing environments and toolkits to allow people to design and produce their own objects (De Mul, 2011; Press, 2011).

4.8.5. Copying ain't cool

Open source hardware faces a real challenge from competition; that is, a competitor seeing an innovation is at liberty to copy the work that an entity has produced verbatim. This appears a major weakness; however Cuartielles (2012) would disagree that copying is inherently bad; indeed, Arduino (the company Cuartielles co-founded) is a 'knowledge exchange company' – with more than simply hardware as a focus. Arduino as a company has developed the programming environment, but more importantly a community of makers surrounding these artefacts; these individual aspects were created around the idea of '*learning something new*' (ibid).

Cuartielles is very open about derivatives; even clones- '*you have to be ready to embrace, what others will build upon your stuff*'. This is not seen as an inherently negative trait, as those users of clones or derivatives are still interacting with the website- still participating in the forum, and driving the growth of the Arduino brand, company, and community. This is in practice, free advertising for the official Arduino boards. The scale of the cloning is alluded to by Cuartielles, although exact figures are impossible to compile since Arduino themselves do not know how many of their users are actively producing artefacts with Arduino boards. In the figures that Cuartielles gives in his talk, there are 1,000,000 unique users to the Arduino website per month. There are approximately 500,000 Arduino boards in existence, meaning

that at an extreme estimate there is a rate of cloning running at 100% of the production of the official boards. In practice however, this is not the case.

The original Replicator 3D printer from MakerBot has clones that are for sale, in the same way that there are clones of the Arduino boards[13]. One of the most public examples of these Replicator clones was the Tangibot, a Kickstarter.com campaign run by Matt Strong in August of 2012 (Flaherty, 2012). The Tangibot was a straight clone of the MakerBot Replicator, but sold for between $500-$700 less depending on the model configuration. Strong used his previous engineering experience to source the components and manufacture from China, rather than Brooklyn, NY that MakerBot chose as their base of operations. This engineering of the process rather than the product split the community of open source hardware advocates.

Torrone (2012) discusses the 11 'Unspoken Rules of Open Source Hardware', in which are summarised some of the principles that guide the recent open source hardware initiatives. While this piece is Torrone's summary, the 'rules' have been cited by proponents of open source hardware (in some high-profile cases, as discussed in the next section) and as such these shed light on the culture of the makers. These rules cut across the licenses that are used by open source proponents (whether software, hardware, or other mediums) and even whether they are pragmatists or idealists when it comes to open source.

[13] Not all clones of Arduino boards are straight copies of the Arduio. For instance, some are re-engineered to perform the same task (even being compatible with the Arduino libraries and compiler software), but take up a much smaller footprint, or cost substantially less. A good example of this can be found here: http://hackaday.com/2013/07/10/build-a-bare-bones-arduino-clone-which-maximizes-its-use-of-real-estate/

The 'Unspoken Rules of Open Source Hardware' are:

1. *We pay each other royalties, even though we don't need to.*
2. *We credit each other, a lot.*
3. *Naming: be different. It's better to be unique.*
4. *We actually do open source hardware.*
5. *Basing your project/product off open source? Open source it.*
6. *Code and designs: add value.*
7. *Cloning ain't cool.*
8. *Support your customers.*
9. *Build your business around open source hardware.*
10. *Respect the designer's wishes.*
11. *When we finally get an open source hardware foundation, we'll all support it.*

Torrone couches these rules in an ideological stance that is difficult to reconcile to a hybrid open/closed model of open source in the sense that Leadbeater (2009), overtly mentions, or the hybrid models exhibited by open source software in the vein of West, (2003). Rule number 5 precludes this use, with a direct link to a GNU GPL (General Public Licence) which allows for the free sharing of code, but precluding that same code (or derivatives of it) forming a part of a proprietary system.

In creating the Tangibot, Strong 'violated' rule number 7; he also skirted:

- Rule 2, by tying the Tangibot to MakerBot's quality, but only insofar as to reassure potential customers that the Tangibot was as reliable as the model it was cloned from.
- Rule 6, as by producing the Replicator clone in China, he successfully reduced the cost of the Tangibot. However, the clone did not add to the design of the machine, and indeed, the additions that Strong referred to future Tangibots were not shown prototyped.

Strong did not act illegally with regards to the license that the Replicator source files were released under, but according to a significant portion of the open hardware community he acted unethically. This is reflected in the comments about 'outsourcing jobs to China'- yet also a number of open source hardware proponents stood by Strong's decision to release a cheaper clone, although Flaherty suggests Strong should have value engineered a generic RepRap 3D printer.

4.8.6. Thingiverse.com terms of service, and the MakerBot Replicator 2 debate

On the 19th of September 2012, MakerBot launched the Replicator 2 desktop 3D printer. Hailed as MakerBot's 'Macintosh moment' (Anderson, 2012) this printer was billed as the first 3D printer from MakerBot that was about enabling people to focus on the creation of artefacts, rather than being interested in 'tinkering' with the machine itself. However, this focus came with a price- the Replicator 2 3D printer is no longer open source hardware.

Pettis is quoted as supporting the free sharing of ideas (4.8.1, p 68), about the importance of this sharing. This apparent change of direction for the company did not go unnoticed; neither did the changes to the terms and conditions of use for the Thingiverse.com site[44].

The backlash from the terms and conditions change led to a blog post by the MakerBot In-house legal council Rich McCarthy (2012), detailing the reason for the delay in posting the human-readable Terms and Conditions for the Thingiverse.com site, and also the specific item that had caused the problem with a number of members of the community.

The problem stemmed from certain incompatibilities with international legal rights governing ownership- for instance the French idea of Moral Rights (in relation to an artefact created by an individual). McCarthy cites a specific case from 1989, where an author ghost-wrote a novel for a fee (which was collected), and then the author sued the publisher, relying upon France's 'Moral Right' attribution to win the case and have their name associated with the novel. This has implications for the website, insofar as this would block another user's attempt to derive a product from the original; as Moral Rights give the author the right to:

> *"to object to derogatory treatment of the work or film which amounts to a distortion or mutilation or is otherwise prejudicial to the honour or reputation of the author or director". (United Kingdom Intellectual Property Office, 2008)*

This appears to be a legal barb in the side of a derivation of a person's artefact, since with the legal precedent cited by MakerBot's council and this provision for the Moral Rights of the copyright holder (and since Creative Commons is built on existing Copyright legislation, this would not supersede) the decision to include the waiver on Moral Rights[45] for the author appears pragmatic on the part of MakerBot, as this covers them from being the potential subject of a legal challenge in a territory which has Moral Rights for physical artefact creators.

The response from MakerBot concerning the openness of the Replicator 2 3D printer was not initially so forthcoming as the response to the Thingiverse.com Terms and Conditions. Pettis wrote a blog post on the 20th of September 2012, a day after the launch of the

[44] The controversy surrounding the Thingiverse.com terms and conditions resembles a similar controversy surrounding the cloud storage startup DropBox a year before. In July 2011, DropBox changed the Terms of use for their service with legal wording that gave the impression the company claimed ownership of the user's files. The company posted twice on the subject for their Blog, and eventually revised the Terms of use- including a summary page that lays out the company's ethical stance on the user's data. See https://www.dropbox.com/terms for more information.

[45] It is worth noting though, that in the UK Moral Rights *do* apply for content creators, but *not* for content that is computer-generated (Section 79, Chapter IV, 1998). As such, the clause in the Thingiverse.com Terms and Conditions are legally superfluous to UK users.

Replicator 2 3D printer, attempting to answer some of the criticisms levelled by members of the Open Source community- entitled *Fixing Misinformation with Information* (Pettis, 2012). Specifically, Pettis wrote about 2 questions that the community were asking. The first concerned the Replicator 2, and whether it will be open source, and the second centred around the Thingiverse.com Terms.

4.8.7. Open Source *Almost* Everything

Pettis was accused by the commentators on his blog post of not directly answering the question about the Replicator 2, and on the 24th of September wrote another blog post entitled *Let's try that again* (Pettis , 2012a). Pettis here is more candid in his response to specific aspects of the position MakerBot took with the design of the Replicator 2. For instance, he notes that the hardware of the Replicator 2 is very closely tied to the hardware of the previous generation (open source) Replicator 3D printer.

> *The electronics are nearly identical to our original Mighty Board electronics, the extruder is nearly identical to our original Replicator extruder with only minor tweaks to optimize manufacturing of injection molded [sic] parts. Update: What that means is that the Replicator 2 core technology is open. (ibid)*

Throughout this response to the critical voices of the open source community, Pettis makes the case for weighing business decisions against the requirements for open source hardware production. Pettis cites Preston-Werner (2011) and Seidle (2012)- both of whom run successful open source businesses. Tom Preston-Werner runs the software repository Github, and Nathan Seidle runs the open source electronics developer Sparkfun[46]. In both of the talks cited by Pettis, the founders of these businesses describe their struggles with running open source companies- Preston-Werner describes his approach as 'open source almost everything' (ibid). This begins with the mindset of developing the components of the business as if they are to be open sourced at a later date, even if this will probably not be the case. This mindset means that the code produced will have the attributes of open source code (that is, modular, efficient and lean) even if the code remains closed. From the 5 conditions that can be used to determine whether a project should be open source specified by Raymond, (2001c), Preston-Werner gives a simple binary choice:

> *"Don't open source anything that represents core business value." (Ibid)*

In the case of Github, this translates as the architecture underpinning the community, but not the tools that the community uses.

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[46] Seidle describes the conflict between open and closed source projects in relation to the hardware that Sparkfun produces. Sparkfun is a successful open hardware company, with a turnover of $75 million USD in 2012 and a workforce of 170+. However, Sparkfun is unique in that it doesn't hold a single patent for the hardware that it produces- and all of the plans for their work are available. Seidle himself estimates that there is a 12-week lead-time on a Sparkfun release before a competitor produces a clone. Seidle describes this environment in positive terms however; he uses the metaphor of 'patent obesity' to describe companies that hoard intellectual property, with Kodak mentioned for their original patent on digital imaging (Lloyd & Sasson, 1978), which Kodak 'sat on for 20 years' (Seidle, 2012). Sedle contrasts this behaviour with Sparkfun, who release early and often (like open source software).

Pettis quotes Torrone's (2012) 'Unspoken Rule' number 7: 'Cloning Ain't Cool'. Yet, does not directly address another of Torrone's rules (Number 5 - 5. 'Basing your project/product off open source? Open source it.') in light of the Replicator 2. Pettis highlights the fact that the Replicator 2 has core technology that is based on open source hardware (the Replicator 1, and it's direct lineage to the RepRap initiative), this could represent a move towards a hybrid model of open / closed development. An *open parts* strategy (Raasch et al., 2009), where commodity technologies are open source, but the portions of the product that differentiate the product remain proprietary.

Makerbot were acquired by Stratasys on the 19th of June 2013, in a deal worth $604 million USD[47], after raising $10 million USD in venture capital shortly before releasing the Replicator 2 printer in September of 2012. Pettis remarks in his blog this marks uncharted territory for open hardware producers. MakerBot have chosen to build a closed source fork of an underlying open source hardware, which resulted in vocal and sometimes visceral condemnation from open source proponents (Průša 2012, Smith 2012, Giseburt 2012, Brown 2012), yet also provoking measured feedback from Igoe (2012) who like Raymond, (2001c) appeals for a more pragmatic view of the Replicator 2 release:

> *"MakerBot is one of many companies working to establish source principles in mainstream corporate culture. Doing that means a lot of compromise. There will be steps forward in the direction of openness, and there will be steps back. There are a lot of people in the corporate world who need to be convinced that open source is a good thing." (Ibid)*

Igoe here suggests that open source hardware is at the point open source software was before Netscape decided to open-source it's code for the Navigator browser, in that the 'corporate world' there is a reticence to see open source hardware as a profitable endeavour.

According to Dahlander & Gann, (2010), the type of 'openness' exhibited by Makerbot was *Sourcing* and *Revealing*; that is, a non-pecuniary inbound innovation source (sourcing) and a non-pecuniary outbound source (revealing). The project was intimately tied with the open source RepRap community[48]. However, after MakerBot made a move towards open innovation (rather than open source) by closing the Replicator 2 'source code', the model was primed for Stratysis to *Acquire* MakerBot.

4.9. Medical Products, and open source

Open source hardware has yet to make its debut in the medical device sector, yet the calls for greater scrutiny for the security of medical devices is growing. Recently, the Food and Drug Administration in the United States of America released an open warning on 'cybersecurity for medical devices and hospital networks' (Food and Drug Administration, 2013), and the

[47] The acquisition consists of $403 million USD for 100% of MakerBot stock, and the further $201 million based on performance over the 2-year period between 2013-2014. From: http://investors.stratasys.com/releasedetail.cfm?ReleaseID=772534

[48] The original Cupcake CNC was billed as an improvement to the RepRap derivatives of the day, since it used laser-cut Plywood instead of a threaded-rod space frame. The Plywood was easier to assemble in a reliably square arrangement, giving greater accuracy and reliability of build.

death of the prominent and well-respected hacker Barnaby Jack has brought this issue to the fore as Barnaby was due to present his work on uploading malicious code to implantable (but wirelessly enabled) medical devices at the Black Hat security exposition in 2013.

4.9.1. Software

There are a number of factors that contribute the increasing risk of compromise for medical devices- that they are increasingly relying upon software (instead of electro-mechanical processes), that they are becoming more complex, and the introduction of wireless internet radios to facilitate remote monitoring and access (Hanna, 2011). The issue of cybersecurity for medical products has been mentioned since 2006 (Bellissimo, Burgess, & Fu, 2006), The computer security community has shown significantly increased interest in implantable medical devices (IMDs) in the last few years (Feder 2008, Halperin et al., 2008, Clark & Fu, 2012). Karen Sandler, the Executive Director of the GNOME project[49] discussed the need for open source development of medical device firmware, in order to bring the bugs to the fore in shorter order than if the code remained proprietary (Stilgherrian, 2012); this call for open source code to form the basis of the development for medical product firmware is reflected in a paper 6 years prior to the interview with Sandler (Bellissimo et al., 2006).

4.9.2. Hardware

The same imperatives for developing open source hardware for medical products do not necessarily apply. The issue of hardware security for a medical device, or its defences against a software hack are not necessarily directly applicable. The opportunity to modify the physical attributes of the device could have significant benefits for the user. This could be the use of a different material to house the device, or a different, more personal interface (perhaps bespoke facemask / mouthpiece tailored to an individual's body topography).

Here the case for open sourcing the hardware follows Raymond's (2001c) conditions. The methods by which a 3D printed casing, or structural element are not necessarily core business strategies of the medical device manufacturer, but could form business models around the core functionality of the device. This means that the medical device manufacturer could follow an open parts strategy to retain control of the basic, fundamental operating aspects of the device, and still have the opportunity to relinquish complete control of some of the other aspects of the design (thereby accelerating the development of those, or improving on the breadth of options available for consumers).

[49] GNOME is a graphical user interface that runs atop a GNU/Linux operating system, bundled with programs for viewing movie files, editing pictures, along with other programs for productivity and such. GNOME is *Free* software – that is, the code is freely available under the GNU public licence. Many different entities develop for GNOME, including individual programmers, and big corporations such as Red Hat Linux. Karen Sandler previously worked for the Software Freedom Law Centre, a body that gives legal representation to *Free* software developers on a pro bono basis.

4.10. Chapter Summary

Open Design is a nascent movement in the wider field of design. The previous chapter discussed Participatory Design, and the benefits this brings when designing in a health context, full of Wicked problems and with multiple stakeholders to engage. While not necessarily a participatory methodology, Open Design nonetheless offers some striking opportunities to enable participation.

The distributed nature of the design activity means that the collaborators can be in any geographic location, enabling participation for those who are currently barred; the infirm, the immunocompromised, those with taboo conditions, those with rare conditions (living great distances from each other). Open Design also promises to mitigate the factors that bar people from participating in the design of medical products (apart from cystic fibrosis, and when the person's condition doesn't specifically limit their collaboration).

For instance, Open Design requires fewer resources to leverage a potentially international community of collaborators than a traditional Participatory Design project, since the work is facilitated and enabled by using the Internet – the objections highlighted in Karlsson et al., (2011) & Money et al., (2011) for including users in the design and development of medical products are mitigated. Also, the benefits of allowing the community to dictate the direction of the design and development process (Owens et al., 2011) can be harnessed using an Open Design methodology.

Moving beyond the benefits to individuals in a medical context, there are opportunities for other stakeholders in the process too, since Open Design allows for the creation of 'niche networks' around products, services or even whole organisations. Properly nurtured by the parent company, these can be the source of new product developments, product evangelists and even peer-to-peer support.

The adoption of an Open Design methodology to product ideation requires that a corporate entity take a different approach to their 'intellectual property'- or even their underlying business model. This is not to say that Open Design and more traditional product development strategies are mutually exclusive, as Open Design could be deployed as part of a multifaceted development process involving 'open' and 'closed' approaches.

There are still significant untested arenas for Open Design; not least the regulation of a distributed manufacturing approach, the legal notion of ownership and remuneration for contributions, and the still-developing definitions and practices of open-source hardware. These form the basis of the required future work to establish Open Design as a viable product development methodology.

This chapter has outlined the definitions, spaces and controversies that play a part in this nascent field. The model of *The Orchestra* (Atkinson, 2011; Nambisan & Sawhney, 2010) for organising the development of the study, where an online community of people who live with a chronic condition excluding them from participation in design activity is empowered

to collaborate on product development. This community may form a 'niche network' (Boyd & Ellison, 2007) around an existing product or service- and although the work may utilise physical locations for the design activity (section 4.5, p56), fundamentally this work will be facilitated by web-enabled technologies for communication, dissemination and production (e.g. Distributed Digital Manufacturing).

5. Study

This chapter outlines the work that was conducted, not only in the main case study for the PhD, but also the work that led up to it- chiefly, the work carried out while the researcher was under secondment to the User-centred Healthcare Design (UCHD) research group. In attempting to create an Open Design platform for people living with a chronic condition the researcher gained invaluable insights for developing the case study central to this thesis. The work for the PhD has also been informed by the researcher's inclusion in other research projects within the wider Lab 4 Living research centre here at Sheffield Hallam University.

This chapter also answers the research question, which was developed through the Doctoral Committee at the 2012 Participatory Design Conference (PDC). Initially at PDC there were 4 research questions for the PhD:

1. Can Open Design have a role in the development of personal medical devices?
2. If so, where in the development cycle is Open Design most appropriate?
3. What is the best way to deploy Open Design- what methods work best in medical product design?
4. What are the barriers to Open Design in medical product development?

In conjunction with the Doctoral Consortium at PDC, the review of the literature for Open Design and Design in Health narrowed down the 4 questions to a single, overarching question to frame the research (Section 1.1.2, page 8):

> *How can people who are barred from Participatory Design through living with a chronic condition be included in the design and development of medical products?*

The questions preceding PDC focus *on* Open Design, rather than the *function* of Open Design. It is this function – the enabling of participation – that is key to this thesis. The practicalities of this research question are dealt with in the final chapter.

The core of this chapter is the main case study, which represents the mainstay of the practical work undertaken during this PhD. The action cycles are highlighted, the process described and the outputs detailed. As such, this chapter builds on the literature and context described in the preceding chapters, Design in Health (Section 2, page 13), Research Methodology (Section 3, page 30) and, Open Design (Section 4, page 47). By the end of the chapter, the process of planning, reflecting, and action involved in the practical design activity for this research is laid out.

Central to the validity of the implementation of Action Research in this thesis is the outline of the researcher's standpoint. This is the collection of preconceptions, frameworks and beliefs that are held by the researcher. In expressing these as recorded prior to the research activity taking place, this fulfils the requirements laid down in the Methodology chapter about rigorous research (section 3.1.1 p 32).

5.1. Overcoming the barriers to participation

Up to this point we have seen the benefits design can bring to health provision generally (or medical products specifically), and the potential Open Design has in the creation of artefacts amongst distributed communities of makers.

The benefits of Open Design apply to many different stakeholders and from the chapter on Design in Health we also see that this diffuse nature of the design activity could be of particular benefit for people who cannot attend conventional Participatory Design events due to health reasons. This chapter sets the scene for the practical work, the theory for which was laid out in the chapter previous. The chapter on the methodology for this research outlines why this practical work can be considered *research*, and why design has been an appropriate engine by which to drive this approach.

In keeping with the requirements concerning the implementation of Action Research and the requirements of Standpoint Theory, the preconceptions and assumptions held by the researcher have been outlined in the Reflective log (and referred to in the thesis). The assumptions and preconceptions date back to February 2012 and were written down prior to the first cycle (**α** phase) of the main PhD case study taking place.

The project involved the creation of a bespoke web space to invite people who live with cystic fibrosis to join, and to collaborate on medical device design. This web space, and the wider project was branded AIR (page 16 of the Reflective Log, Annex A). AIR represents a design Thing – a socio-material assembly of human and non-human entities (section 3.6 p 44).

Recruitment happened mainly via a community champion, who became involved with the project early on and through whom an engaged community of many thousand people was approached for recruitment. Currently, the community stands at 17 people (including the researcher), with 4 active members who have contributed to the discussions. These people form the majority of the content in the site, with the other members providing support and information occasionally (some have not posted).

The research has generated 5 prototype designs, which range in complexity. The earliest ideas focussed around the hacking of existing items, such as Ikea furniture for storage of medical equipment; or the creation of simple products to fulfil niche applications. As the project progressed the ideas became more complex- with more opportunities for collaboration on the individual aspects of the designs. During the duration of the project (the duration the researcher was able to be an active participant), the design Thing AIR was able to create and sustain collaborative design activity. However, not all of the ideas that were proposed were developed. This suggests that AIR required more infrastructuring- more development of strategies to support design after design.

5.2. Scoping Work

In order to better understand how to nurture online community development of artefacts, some research was conducted as part of a wider research project. The results of this have greatly influenced the development of the PhD research, by allowing for the preconceptions held tacitly by the designer to be examined.

In January 2011 the researcher was seconded to help develop an online collaborative platform for the development of research tools (Annex A, p 4). These tools would then be used in a collaborative design project reimagining adolescent Diabetes provision in Rotherham, UK. The project had two broad iterations – 'Phase Zero' relates to the attempted creation of an online community of young people with Type 1 Diabetes (T1D); when 'Phase Zero' was recognised as unsuccessful, the project changed direction and focussed on traditional Participatory Design with support groups[50]. This subsequent work was not part of the researcher's remit, and as such only 'Phase Zero' is described here.

The aim was to increase the attendance rates to diabetes clinics. Since none of the design team had first-hand experience of T1D, we recognised that we did not possess the appropriate knowledge to create some insightful artefacts with which to work with a community of 'disengaged[51]' adolescents with T1D; for example, conceiving of appropriate design games or formats for future workshops was difficult. In fact, adherence to self management regimes (of which attendance at clinics forms an integral part) worldwide is a problem of 'striking magnitude' (Sabaté, p7 2003), with rates of adherence to the level advised by the American Diabetes Association for Diabetes management in the USA at 2% (Ibid, p11).

This project aimed to tackle the Wicked Problem of engaging young people living with T1D in a health service. Although ultimately unsuccessful in it's original intentions, the project itself yielded an interesting and well received service redesign for adolescent Type 1 diabetes services. The project itself formed an integral part in the development of the methods used in the execution of this PhD study, especially with regard to the development of community development and design.

5.2.1. Online collaboration in a design project – 'Phase Zero'

Shown below is the implementation of Action Research in this project, and indeed the process used for AIR – the main PhD case study. **Error! Reference source not found.** represents the cyclic nature of Action research, and is based upon Checkland & Holwell (1998). For more information on the use of Action Research in this study, see section 3.2 (p 35).

[50] This enjoyed far more success, and became the 'Whose Diabetes is it?' service prototype. See http://www.uchd.org.uk/uchd-in-action/young-people-with-diabetes for more information.
Disengaged is a term used by medical staff to describe a person who does not adhere to their management program for their chronic condition.

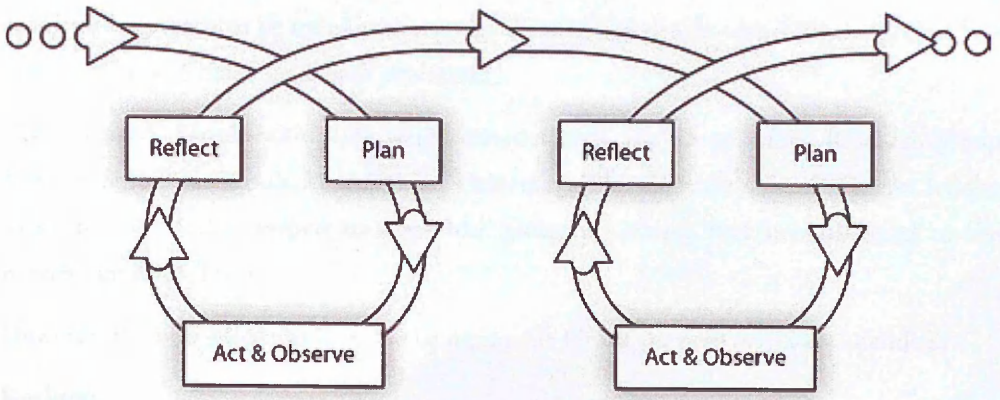

Figure 8 - The structure of the action cycles for 'Phase Zero' and AIR

Planning:

The project was influenced by online community based research conducted by Füller et al (2006), which engaged members of a community in a collaborative exercise to redesign products. As such, UCHD sought to develop a similar community space, and engage in a similar act of co-creation.

This required the creation of a web space to facilitate this collaborative design activity. The preconceptions of the research team (designer[52], a clinical research lead, and a computer scientist) were recorded and used as a basis for the planning and development of the web space. These included findings from the Füller et, al. (2006) paper, but also contextual research from bloggers with T1D.

The design decisions were taken from cues drawn from the rich material posted and curated by people living with T1D, and a bespoke back-end architecture and front-end experience were developed. This process was extremely costly, and ultimately doomed to only partial success in it's original guise- the project focussed to heavily on observation and interpretation, rather than participation and collaboration.

The production values of the site were high, and well polished. It was a preconception of the research team that this would naturally attract participants to the space. The tools to facilitate the redesign of the service failed to work because they were not built on a participatory foundation- there was no co-ownership of the tools. More fundamental to this however, was the lack of people to champion the idea in the Diabetes community.

Act and Observe:

The development work for the web space took a significant amount of resource, both in terms of project budget but also personnel. The research team settled on creating a web space with bespoke back-end architecture to ensure the experience that was assumed to be necessary. The development setbacks slowed the project down, and meant that by the time a

[52] The Researcher – author of this thesis.

prototype was ready to be tested with a group of 'engaged' people with T1D the project had run out of time to make significant alterations.

The 'engaged' people with T1D were recruited from the Participatory Research group 'Getting Sorted', at Leeds Metropolitan University. The feedback was very useful for the wider project, and it helped to shape the prototype service that was delivered to the Rotherham NHS Trust.

However, the web space was found to be unsuitable for the purpose originally intended.

Reflect:

The most prominent learning point for this PhD was this notion of being 'an outsider' to the Diabetes community. If a person is blogging about their experience of Diabetes, this does not necessarily mean that they are willing to share these discussions or experiences with someone outside of the community. This was a fundamental assumption that the core researchers shared. In the future, a community champion is needed early on- someone to allow for the project to be closely aligned to the needs, desires and ultimately the lived experience of the people that the artefact is intended for.

There were practical lessons to learn also, mostly centring around the cultural differences between involving health practitioners, programmers and designers in the development of a prototype. The site was very expensive to develop, as the whole architecture was bespoke; with some off-the-shelf HTML 5 components modified by the development team, and Wordpress as a backbone Content Management Suite, but the site itself was largely derived from scratch. This goes against the adage 'Fail Early, Fail Often, Fail Cheaply'. More comprehensive solutions for social digital infrastructure exist but were discounted, as these did not provide the functionality that was incorrectly assumed (by the research team) to be critical to the success of the intervention.

Learning from the successes of the previous UCHD project engaging multiple stakeholders in the redesign of the medical outpatients service (Wolstenholme et al., 2010), and the success of co-researchers drawn from the user population (Chamberlain et al., 2011), whilst also taking on board the failures from the Diabetes collaboration tool has meant greater success in the implementation of this PhD research.

5.2.2. Collaborative Design | PhD Research – Transition from MPhil to PhD

The PhD began with a focus on how to improve collaborative efforts for the development of medical products, by examining existing 'gold standard' frameworks for the inclusion of 'end users' (Shah & Robinson, 2008) in the development of medical technology.

As we have seen, there are moral and pragmatic reasons for including people in the design process as collaborators (Carroll & Rosson, 2007; Müllert & Jungk, 1987), and therefore fostering 'genuine participation' (Arnstein, 1969; Hess & Pipek, 2012; Kensing & Blomberg, 1998; Luck, 2007) in the design of medical products (via collaboration (Sanders & Stappers,

2008)) is an important aim. Thus, the focus of the PhD developed past the User-Centred techniques of my Masters as a result of the literature and contextual work.

In their use of novel collaborative techniques to design the *Future Bathroom* (Chamberlain et al., 2011; Chamberlain, 2010) the researchers found problems with discussing taboo subjects with the project partners. Toileting habits are naturally very personal, but the difference in age and sometimes gender presented a problem to the design / research partners. Community researchers were trained; who as peers of the older partners in the project could gain access to the lived experience- rather than being made to feel awkward by discussing sensitive, personal topics. Anonymous feedback proved especially valuable, since if people feel unobserved they are much more candid and honest. The metaphor of bathroom graffiti was used to produce an interactive exhibition to elicit such feedback (Chamberlain & Yoxall, 2012), the results of which could be combined with the data gathered from the community researchers.

As we see from the Open Design chapter (section 4, p 47) the diffuse, distributed nature of the design process (as facilitated by the Internet and Distributed Digital Manufacturing) means that in the case above, the project partners could choose to remain anonymous in their contributions to the design project, whilst still being enabled to participate (given the appropriate internet-based tools). Open Design promises a solution to their participation in collaborative design.

5.2.3. Cystic fibrosis

As part of the research into the 'engaged' community of Diabetes, there were a number of blogs around life with cystic fibrosis- people who live with cystic fibrosis are at risk of developing Cystic Fibrosis Related Diabetes (CFRD), and as such must deal with the self-management of (effectively) 2 chronic diseases.

This was compounded upon meeting the cystic fibrosis clinician that co-leads the ward at Sheffield Teaching Hospitals NHS Trust, and hearing about the different ways that design could be used in the development of artefacts to assist those with cystic fibrosis in their self-management.

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. 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 *Pseudomonas aeruginosa* bacterial infection (amongst others), contracting this infection 'accelerates the deterioration of pulmonary function, increases hospitalisation and reduces life expectancy' (Griffiths et al., 2005).

One of the impacts of living with cystic fibrosis is a reduced ability to absorb nutrients from digested food. As a consequence, people with CF must take digestive enzymes with their meals. The amount varies depending on the type of meal. One of the major problems with this process is that is can be difficult to record when enzymes are taken, or what dose was given. The current containers that are distributed by Pharmaceutical suppliers rattle, and the stigma of shaking out the correct number of enzymes when out for a meal was highlighted in the discussions with the hospital staff here in Sheffield. The main supplier of enzymes in the UK is Abbott Pharmaceutical, with their Creon brand. This is in the form of a capsule, rather than a pill. These capsules are very light, and prone to distort under pressure. They are also sensitive to moisture, and will warp, swell and dissolve if exposed to water- all considerations to bear in mind when developing a dispenser.

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- particularly as the medical models for treating cystic fibrosis vary in different territories, with different pressures on people who live with cystic fibrosis who dwell in countries with different models of healthcare provision. Open Design offers the opportunity to develop low-cost solutions for common problems associated with the self-management of chronic conditions. This might include the 'hacking' of existing equipment, but it also could exploit Distributed Digital Manufacturing to produce bespoke artefacts or copies of existing equipment, modifications, perhaps entirely new concepts.

Open Design also offers the opportunity to develop individual artefacts as a response to a particular, individual need. This individual need could form the basis of a more widely generalisable solution- and the open source foundation of the designs means that the dissemination of prototypes and ideas is easily facilitated.

5.3. Open Design case study - AIR

This section relates to the Open Design community created to collaborate on medical product prototypes, as the main practical research component to this PhD. The community's activity is recorded online, in a publically accessible web space at:

http://airdesignspace.ning.com

This web space, the artefacts that it describes and the conversations it contains should be considered one of the practical research outputs to this PhD, and referred to with relation to the description and expansion below. AIR is a design Thing comprised of the researcher, participants, web space, tools, and the artefacts that were created as boundary objects, and prototypes.

In order to provide a first attempt to design medical products using Open Design, a community was needed. This would use the available 'off the shelf' options available from vendors of social network software to avoid the problems outlined in section 5.2.1 (p 83), and also in the Reflective Log (Appendix A, p 4).

The community space created was branded with the name AIR (Appendix A, p 16). This included a colour scheme and logo that was used for the web space, and also the physical artefacts posted out to the different participants. The case study is known eponymously in this thesis as AIR.

The difficulties in recruiting people to the diabetes community (Appendix A, p 5) highlighted one of the largest challenges to the research- Open Design is a collaborative activity, and if the recruitment of participants failed then the community space would be barren. This in itself would provide valuable data, since a negative result is still an answer to the research question posed in the Introduction (section 1.1.2 p 8).

The importance of a community 'champion' was apparent from the previous research, someone who understood the research aims, and was willing to act as an ambassador for the research to other members of the wider cystic fibrosis community. A 'champion' for the community was necessary to design the site too, since this was again highlighted as an important failure of the initial diabetes design work.

5.3.1. Action Research

The previous sections (1.1.1 p 6, & 5.2.2 p 85) outline the link between the previous Masters work, and the early planning for the PhD case study (AIR). This section describes the research in the terms laid down from the previous chapter, by outlining why the practice outlined here can be considered research.

The recording of assumptions and preconceptions, as well the record of the practical work are all requirements of the Action Research process (Archer, 1995; Avison et al., 1999; Checkland & Holwell, 1998; Reason & Bradbury, 2005) and as such these were documented in February 2012.

The Framework (**F**), Methodology (**M**) and Area of Interest (**A**) (Checkland & Holwell, 1998) are laid down to ensure rigour in the research process (3.1.1 p 32):

- **F**: The framework of ideas comes from the collective sensemaking involved in understanding the lived experience of the chronic disease (cystic fibrosis), and the opportunities for design. This collective sensemaking is Social Constructionism (Crotty, 1998), informed in this case by an HCI implementation of Feminist Standpoint Theory (Bardzell & Bardzell, 2011; Bardzell, 2010).
- **M**: The methodological approach in this research is twofold. The work is considered research since it is guided by the principles of Action Research (Archer, 1995). The practical design is guided by the methodology of Open Design; and also

Participatory Design more broadly (Simonsen & Robertson, 2012; Spinuzzi, 2005). This is the Realist endeavour that means physical artefacts are created as a response to the more relativist creation of sensemaking in **F**. This is held in tension via design practice – a collaborative act of making in response to the individual standpoints of the participants.

- **A**: The area of concern – enabling participation in the development of medical product prototypes for those excluded due to their chronic condition (cystic fibrosis). The methodology Open Design is used to mitigate this.

5.3.2. Ethics

Archer (1995) highlights the problem of ethical working for the designer using Action Research, as the work necessarily involves collaborating with others. AIR avoided the recruitment of participants via the National Health Service (through any channel, or by any representative) and instead focussed on recruiting participants in their capacity as individuals (rather than in their capacity as patients) via private channels.

NHS ethics applications are lengthy, and novel research falling outside of the Evidence Based Medicine paradigm is challenging to fit within the established guidelines; this was keenly felt by the researcher during the scoping work conducted on the diabetes project (Phase Zero). In recruiting people for the research via social media, and other public forums Sheffield Hallam University's ethics and governance procedures were sufficient[53].

The requirements for the ethics application were that the site be started as 'open access, closed door', meaning that anyone was invited to participate, but had to be allowed access to see the site's content, and to post or adapt that content. An 'informed consent' process was put in place, with a static website used to inform participants (discussed later), but also a paper-based form (see Appendix C).

This was problematic in the sense that for the Open Design concept to be tested, access to the site, discussions and content had to be freely available. As such, a further application was made in the site to the Chair of the Faculty Research Ethics Committee to open up the community to free membership; this application was made at the end of the beta phase of development in AIR, to demonstrate that collaboration in the site was not harmful or detrimental (section 5.3.2 p 89).

5.3.3. Researcher Assumptions, and personal framework

Since as the researcher is unable to be completely detached from the research findings, it is therefore necessary to highlight the preconceptions that are held about the research as a result of the reading and prior research.

[53] Ethics approval was sought via the Cultural, Communication, and Computing Research Institute (C3RI) procedures within the Arts, Computing, Engineering and Sciences faculty of Sheffield Hallam University. This was submitted at the juncture in the PhD when the research transitioned from MPhil to PhD, after the first year of research- and subsequently revised and authorised by application to the chair of the C3RI ethics committee as the scope of the case study developed.

It is also worth noting the researcher's standpoint, since this forms the foundation through which the world is experienced and therefore how the results are interpreted. As a White, male Christian the researcher's personal ontological and epistemological framework for understanding the world is perhaps different from the participant's. However, it is the researcher's belief that their ontological and epistemological worldviews as stated are not mutually exclusive to a Participatory Worldview, as discussed by Reason & Bradbury (2005), or the underlying principles of Participatory Design (Kensing & Blomberg, 1998; Kvan, 2000; Müllert & Jungk, 1987; Spinuzzi, 2005).

Similarly, as recorded in the document containing the researcher's reflections of the research project in mid February 2012 the following list covers the assumptions held by the researcher (Appendix A, p 10). These are influenced by the scoping work that was undertaken at the beginning of the PhD (Phase Zero Diabetes project); particularly based on the community work by Füller, Bartl, Ernst, & Mühlbacher, (2006):

1. *That this will be an interesting and engaging way for people to participate in the design process*
    a. *People will want to participate… if I have a champion*
        i. *Assuming the lessons learnt from Diabetes Phase Zero are applied*
2. *The process will come up with some novel concepts*
3. *That cultivating and sustaining activity will be hard work (Suroweicki, 2005)*
    a. *The correct tools should be employed – Suroweicki suggests Wikis*
4. *In order for people to engage and work with me in this, the production value of the work must be high*
    a. *People must feel welcomed into the project, and that the work is serious*
5. *The right tools need to be supplied to enable participants to express their ideas*
    a. *Or, that tools need to be supplied at all*
    b. *These tools are an extension to the idea of Toolkits for Innovation and Design (TKUID) used in Mass Customisation*
    c. *These tools are comprised of a physical aspect, and software*
        i. *Pens & 'traditional' design tools*
        ii. *MineCraft Print & SketchUp*
    d. *People will find creative reflection difficult*

In recognition of the feedback from the scoping work 'Phase Zero', and the understanding of the researcher that the tools for production should be made as accessible as possible the use of novel methods for creating CAD files was initially proposed. The Tool MINECRAFT.Print() is a small computer script developed by two students at MIT, and it allows for the creation of 3D CAD data from structures built in the computer game *Minecraft*[54].

[54] Minecraft is a simple computer game where players place or mine blocks in a randomly generated landscape. The game has been likened to playing with Lego, and since it's initial development began in early 2009, the game has been wildly successful. See more at: https://minecraft.net/game

This CAD data can be printed via 3D printer, meaning that instead of having to use complex commercial (or open source) CAD software a participant could instead play Minecraft and then 'export' their creation. This proved problematic however, as MINECRAFT.Print() is only available as a command-line script (there is no Graphical User Interface (GUI) version available). Ironically, this means that the CAD data is easier to create (since the game Minecraft is used), but harder to export and print (as knowledge of the Python programming language is required). At the time of writing the assumptions, and planning AIR, a GUI version of MINECRAFT.Print() was in development, but this did not materialise.

5.3.4. Structure

The activity in the main case study happened in Action Cycles, of planning, action and reflection. These cycles happened through the period of the case study, with a cycle prior to the case study (Phase Zero), then through the evolution of AIR (**Error! Reference source not found.**, p 84).

Shown below is a timeline, showing the different development cycles of AIR- and the action cycles these represent:

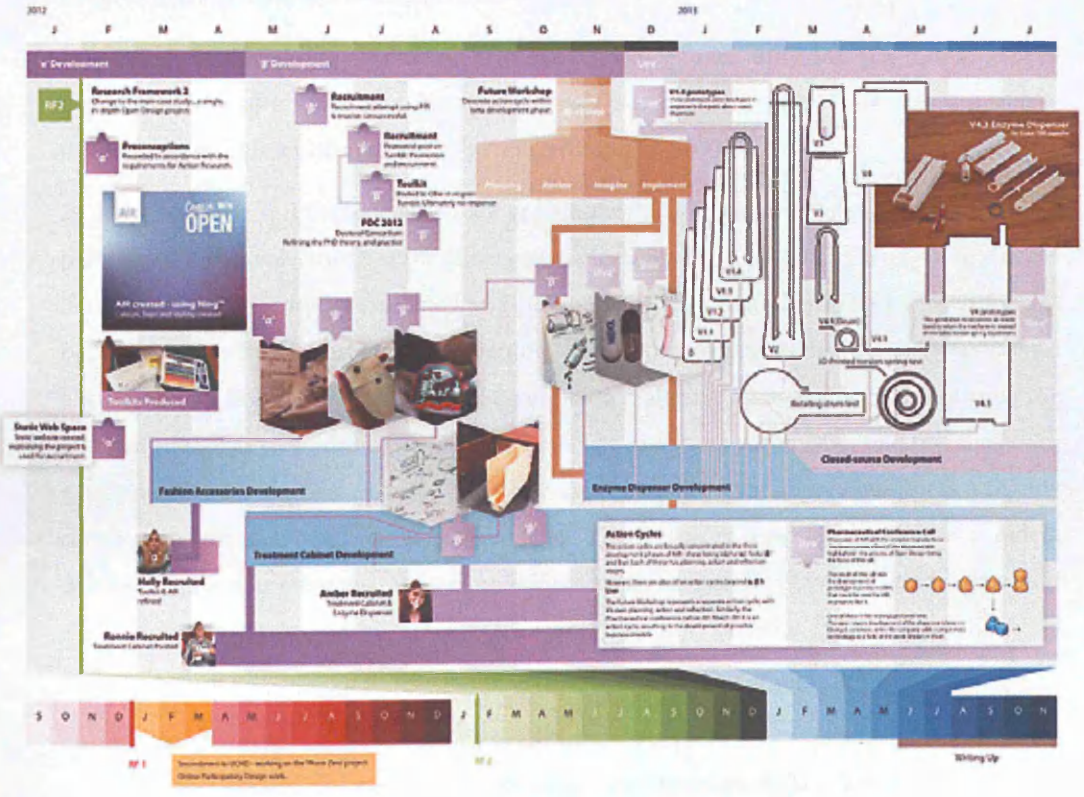

Figure 9 - AIR 'Open Medical Products Methodology', showing development phases (top) and relation to PhD (bottom). Full size version at Appendix B)

AIR is a design Thing (see section 3.4 p 42)- a socio-material assemblage of human and non-human entities. Viewing AIR in these terms allows for the explicit infrastructuring of the

project to extend beyond the design of the products; AIR as a platform could be sustained without the input of the researcher- the architecture of the site could be 'passed over' to the fellow collaborators. The reliance on open-source 3D printing also lowers the barrier to the methods of production, and while the participants might not have access to these tools themselves (at home), access via community spaces is increasing and it is not inconceivable that a community space would be available in the near future.

The reflections from the period of the study are recorded in the Reflective log in Appendix A (p 10 onwards), and can be used as a reference when reading the summaries of the Action Cycles as described below.

5.3.5. α – Alpha Development Phase – first Action Cycle

Planning:

From the previous work conducted for the Diabetes project ('Phase Zero' – section 5.2.1 p 83), it was apparent that spending time to create a bespoke solution that exactly matched a set of imagined criteria was a poor use of resources. Instead, a modular platform for creating bespoke social networks was chosen from the vendor Ning™. Although Ning™ networks are proprietary, they offer a good deal of communication and sharing tools, as well as the ability to customise the look, feel and interaction of the site.

It is the researcher's own experience, that the amount of time and effort put into aspects of the research project that face the participants has a direct impact on the way those participants feel about being part of the research.

In order to satisfy this preconception about high production values influencing how a person perceives their involvement, some time was spent branding the initial site. Due to budget limitations, this activity was directed and produced by the researcher. The research for this branding came from the blogs documenting the lived experiences of cystic fibrosis- whilst also creating a brand that evokes a feeling of being malleable, changeable and capturing the ethereal nature of new ideas. As such the space was given the name AIR, and matched with a colour palette, fonts and textures to evoke a space that gave the impression it was a slightly rough space for people to add their own ideas. The feeling of a pristine space was avoided, due to the preconception that the community members would be reluctant to add content if the site already appeared 'finished' - a finding from the previous 'Phase Zero' Diabetes project, and an observation of Ehn & Kyng (1991).

Surowiecki (2005) advocates the use of Wikis for collaborative development by communities of people, although in the discussions with people who live with T1D following the failure of 'Phase Zero', the use of 'complex' tools like Wikis was discouraged in favour of tools resembling social media sites. This paradigm is well understood, whereas the Wiki format (whilst powerful and open source) was seen as more opaque. From the reflections on 'Phase Zero', the call for tools that resembled the well understood paradigm of 'posting' ideas to a user's 'wall' was specifically mentioned (Appendix A, p 6).

One of the main assumptions to come from the research was the requirement of tools to aid the 'unsticking' (von Hippel, 2005) of participant's knowledge. As such, toolkits were produced to try and aid the process of ideation, as well as acting as a gift for the early members of the community (those joining in the first two action cycles).

The theory involved in making these toolkits came from literature from the field of Mass Customisation, in particular from Franke & Piller, (2004) who discuss the idea of 'Toolkits for User Innovation and Design' (TKUID). Franke & Piller's TKUID exist exclusively as web-based tools for configuring watches, or cars- here the theory of providing 'trial and error feedback' and 'outsourcing design activity to the customer' is translated into *collaborative design* activity facilitated by some designerly tools.

The research into which tools should be included came about from previous research around diabetes bloggers, and from other blog content on the service Tumblr; a social-blogging site that functions in a similar fashion to Twitter (with similar mechanisms for 're-blogging' content, and 'liking' posts, which mirror the 're-tweet' and 'favourite' functions of Twitter). See Annex A, p 13.

The blogs on Tumblr, as well as industry blogs such as Core77 give contemporary, and popular views on design. Blogs such as these set the tone for how design is perceived. Although recruitment via Tumblr proved unfruitful in Phase Zero, the researcher decided to blog about the early stages of the project by starting a Tumblr blog.

Figure 10 - Physical toolkit designed and dispatched to the early participants

In preparation for the production of artefacts using Distributed Digital Manufacturing a MakerBot Replicator 3D printer[55] was purchased for use in the research. Facilitating Open Design amongst a community is difficult at the time of writing, as the number of physical community spaces (Fab Labs, for instance) is small (although growing). Similarly, the number of people with a 3D printer is small[56]; coupled with the fact that there are few people living with cystic fibrosis[57], this means the chances of finding an existing community of people who use 3D printing *and* live with cystic fibrosis is small.

Initially the project plan called for the purchase of five MakerBot Replicator 2 3D printers to be shipped to participants that would be invited to the space individually (Appendix A, p 16). It was hoped that this would act as an incentive to participate, and that these 3D printers would assist in the creation of artefacts, as the access to domestic 3D printers and community workshops is currently not ubiquitous. This option proved too costly, however.

As such, the facilities at Sheffield Hallam University were used to simulate the tools available in a community workshop- using the CNC lathe, router, etc. and the MakerBot 3D printer to produce parts and prototypes that could then be posted to the community members for review. The limitations of this process are obvious, since the participants themselves are removed from the making process. However, this act of collaboratively developing and sharing pieces mimics the process, whilst also enabling the participants to direct the project in a way that is not available to them in a traditional medical product development process (Shah et al., 2009).

At this point AIR comprised toolkits, a web space, and the researcher; these were the elements of the design Thing AIR at this stage. With the requirement for early participation of those who live with cystic fibrosis identified as key, the researcher set about recruiting a community champion.

A person was identified via a friend of the UCHD research group team, and Holly was recruited to participate via an invitation email signposting to a static website that outlined the research project[58]. Holly joined at the end of February 2012, when work on the toolkits and AIR was complete. At this stage, the community in AIR comprised the researcher and Holly.

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[55] This particular brand and model of 3D printer were chosen as it represented the 'cutting edge' of simple, open source 3D printers at the time. The Replicator model was newly released, and was one of the first open source 3D printers to be sold primarily as a completed unit, rather than a kit for user assembly. The Replicator was the last open source 3D printer released by MakerBot, with the Replicator 2 (and subsequent 3D printers) being entirely closed source. See more in section 4.8.6, p 67.

[56] MakerBot have sold 22,000 3D printers since their inception in 2009, with their latest product, the Replicator 2, making up approximately half of this number. MakerBot is regarded as one of the most successful companies to emerge from the rise of domestic 3D printing, having been acquired by the very large 3D printing corporation Stratasis. This number of printers from the largest manufacturer of domestic-orientated (low cost) 3D printers highlights the diminutive nature of the market. Sales data from Stratysis corporate news release (2013). See more at: http://investors.stratasys.com/releasedetail.cfm?ReleaseID=785515

[57] cystic fibrosis affects around 10,000 people in the UK.

[58] This static website was created to inform people who had been invited to participate, either by direct contact from me, or via a passive invite via the social blogging platform Tumblr.com. See more at: http://airdesignspace.businesscatalyst.com/index.html

The use of Tumblr to blog about the early stages of the project was useful here, as Holly also had a blog on the service. The social features of Tumblr allowed for rapid dissemination of ideas, whilst also facilitating research about specific topics. For instance, Tumblr uses the same mechanism as the hashtag (# prefix on a term, e.g. #OpenDesign) to link posts across users and locations. For instance, clicking a hashtag for cystic fibrosis (e.g. #cysticfibrosis) meant that a chronological list of posts by all authors of the service tagged with the same hashtag is generated. These features were crucial to the choice of Tumblr, rather than Blogger, for instance).

Action:

The initial layout of the site is shown below, with the links at the top to aid navigation around the different areas. The Ning™ architecture allows for the creation of web pages that fulfil specific functions- e.g. a Blogging tool, forum, video page, chat function, etc. The main design work was to be carried out in a section titled 'Design Forum'. Each new design proposal by a participant appears here, with the researcher assuming a role in making sure this is kept tidy and up-to-date.

Figure 11 - Screen shot of AIR, during the 'a' stage of development

From the early conversations with Holly, it was apparent that we needed more content to populate the site, for people to engage with. Also, the initial version of the Ning™ architecture in use by the researcher did not provide very elaborate tools for communication, or the means by which to sign in with existing social networking tools. Specifically requested by Holly was the ability to sign in with Facebook, or Tumblr. Also requested were more sophisticated communication tools- Holly specifically discussed the need for a 'chat' feature (internal Instant Messaging within the AIR site). This meant upgrading AIR to the intermediate package, and enabling the features.

Once the features suggested by Holly were implemented, work began on adding content. Following a discussion via the chat feature in AIR an idea for fashion accessories for men with CF was identified as a possible avenue for exploration.

This screen shot (**Error! Reference source not found.**) was taken after Holly and I had worked on some content together. Holly posted a video that she had produced which outlines the difficulties faced by living with cystic fibrosis, as part of the collaborative act of sensemaking. This video was originally produced by Holly for a cystic fibrosis Trust event, rather than being made specifically for AIR.

The tools embedded within the site allow for the posting of rich digital media in a seamless way very much akin to other social media; this was highlighted by Holly as a positive- the site was easy to comprehend and use. This seemed to confirm the choice to use a social media model, rather than a Wiki.

The discussions revolved around fashion accessories, as this was an area that Holly highlighted as an issue for men in particular- since men do not typically carry a handbag with them, which is an issue for storing the different medications and equipment that is required on a daily basis for life with cystic fibrosis.

The discussions in the site were preceded by a BBC TV documentary *Love on the Transplant List* (broadcast 28th November 2011) following the life of a person living with cystic fibrosis and who required a lung transplant. The programme gave vivid depictions about the amount of medication that is required on a daily basis, and also some of the management techniques that require a person's whole daily routine to be altered. Discussing this TV show became another important aspect of this collaborative sensemaking.

The 'alpha' action cycle proved to be very similar to collaborative development of the traditional sort, in that the project collaborators have their own sets of priorities and personal circumstances. The work done with Holly to populate the site initially was very productive, with some good ideas posted.

However Holly left the site for personal reasons, and for a period of 2 weeks the project was in limbo while more recruitment took place. Various options were considered, and links with Patient and Public Involvement (PPI) groups within the NHS were explored. However, PPI involvement for research is concerned with involving people in the design of research

projects, through consultation or perhaps a more participatory approach using methods like PAR (Whyte, 1989). These made the process of recruiting through PPI difficult, as the scope of the work involved was very different.

Early in April 2012, the researcher contacted Ronnie Sharpe at CysticLife[59] (Appendix A, p 21) with an invitation to discuss the possibility of working with his social network on this research. Ronnie was keen to protect his community from charlatans and as such suggested that he himself take part to then assess whether to expose his community to the research. Upon agreement Ronnie was keen to post an idea for himself. From this came the idea for bespoke furniture to organise the equipment required for daily management of cystic fibrosis. In particular, the use of Vest Therapy[60] and the equipment to facilitate this. At this juncture, the site moved out of its 'alpha' phase, with the focus moving to design work and recruitment.

Reflection:

This 'alpha' cycle was shorter than the later 'beta' and 'open' cycles. The planning for the cycle included the construction of the artefacts to act as provocations- the initial toolkit being a prime example, as with the initial AIR web space. The action here involved the collaborative look at these tools, and the planning of the next stage in the research project (recruiting more participants).

In reflecting on the 'alpha' cycle, it became apparent that the critical reflection of the participants might be a problem in the future, although motivation did not appear to be a problem at this stage (quote from Appendix A, p 18 & 19):

> *Possibly the most interesting aspect of the work so far (with regards to the communication with Holly) is that Holly seems keen to invite people and act as a community champion without much guidance from myself.*

The roles for the researcher and the participants were first under scrutiny here. Holly was very invested in the idea, and the initial work as a partner. Here, AIR fell within the framework outlined by Press (2011) as 'The New Design'- a method by which the design activity could be stimulated.

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[59] CysticLife is a community for people who live with cystic fibrosis, based in the United States of America. At the time of writing, there are over 7,300 member of the community.

[60] A key aspect of cystic fibrosis self management is a regular physiotherapy regime. This involves exercises to loosen the mucus that builds in the lungs, usually with the help of a carer. Vest Therapy involves the use of an inflatable vest, which is attached to a compressor capable of oscillating the airflow to vibrate the wearer. This action is intended to augment the carer input, giving the person with cystic fibrosis more independence. This prototype demonstrates the cross-border nature of Open Design and highlights the disparities between different territories and their approaches to healthcare. Vest Therapy is not used in the United Kingdom as it has been shown to be harmful over prolonged use. An entity running an open design project such as this would be required to understand and develop within the boundaries of practice for the territory the products may end up.

The process of running AIR was also discussed during a meeting with the supervisory team. The use of focussed activities within AIR was first discussed as a way of keeping momentum up in the site (quote from Appendix A, p 19):

> *The progress of the first case study has the potential to become slow- the momentum must be kept up with Holly, and it was considered prudent to begin to find other sources of recruitment. As such, I'll look to contacting the organisers of existing cystic fibrosis communities to see if there are any opportunities for collaboration. I will also contact the cf trust here in the UK. Failing these approaches, I will contact CF support groups, and contact Dr. Ade Adebajo about using PPI contacts.*

5.3.6. β - Beta Development Phase – second Action Cycle

Planning:

The aim of this development phase was to grow the AIR community and to broaden the scope of the prototypes, or ideas that were put forth in AIR. This began with adjusting the AIR site with recommendations made by Holly before her departure, chiefly adjusting the background texture and renaming the 'Forum' to 'Design Forum'.

It was expected during this phase to broaden the recruitment activities, and to leverage some portals for research that were used by NHS researchers. These did not require additional ethical clearance, as the people living with chronic conditions are recruited in their capacity as people, not patients. However, proper ethical clearance was sought (via the chair of the ethics committee, and an amendment granted on the 30th May 2012).

In recognition that this development phase would span the summer months the pace of the design work slowed as holidays and clinic appointments for Ronnie followed. This pace heightened the requirement for further recruitment, since a key assumption for the work was that a greater number of participants would enliven the development process.

Planned for this phase was a separate action cycle that would encompass a Future Workshop (Müllert & Jungk, 1987), which followed the work conducted by Francis & Reyes, (2012). The work by Francis & Reyes was presented at the Participatory Design Conference 2012 (PDC 2012) that the researcher attended[61].

Action:

The development phase kicked off with the recruitment of Ronnie, and after he had received his toolkit / welcome pack Ronnie posted an idea for development (quote from Appendix A, p 23):

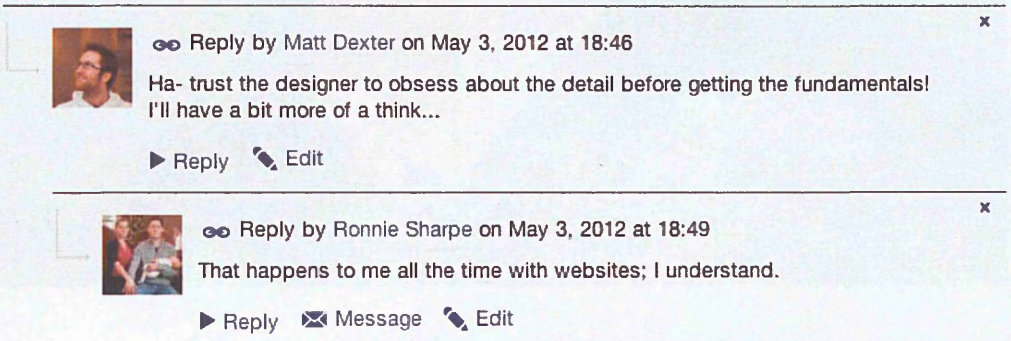
> *So as with many of you, my treatments (i.e. Vest and compressor) are out in the middle of my floor by my desk. I always thought that it would be nice to have a "treatment cabinet".*

[61] The researcher presented at the PDC 2012 Doctoral Consortium. This presentation and the feedback proved key to the positioning of this work, in terms of contribution to knowledge, and the intended audience for this work.

One of the reflections recorded by the researcher at this point was the nature of the inquiry posted by Ronnie. The scope didn't challenge the fundamental operation of the equipment, or attempt to reconsider the use paradigm (quote from Appendix A, p 23):

> *Interesting to see with this post, that Ronnie is continuing the theme of not challenging the very nature of the treatment, but in fact the aspects of which fit into his life. This will be interesting to see whether this bears out in the posts made by other members of the community, and what other ideas come from this.*

At the beginning of the discussions with Ronnie, the researcher (in their capacity as designer) dove straight into the technical minutiae of the problem. This was picked up by Ronnie, and after the researcher apologised it emerged that this 'jumping ahead' was how Ronnie expected a designer to behave (quote from Appendix A, p 24):



Highlighting the collaborative nature of this process is crucial – the conversations were not one-sided, with discussions encompassing various travel solutions and extra features to be accounted for. The limitations of this process were obvious at this stage of the development work, since the AIR community was comprised of the researcher, and Ronnie (quote from Appendix A, p 25):

> *This beta launch of the website meant that the ideas were kicked-off, and there was a genuine dialogue between Ronnie and I in the space. However, this represents only a collaborative effort, distributed co-design, rather than open design. The community needs to grow, and with more people in it, then there will hopefully be more people to develop ideas from.*

The prototype developed in a key direction when the researcher suggested to Ronnie that an insert for Ikea furniture would be a good idea, since this offered more flexibility (Appendix A, p 27). Although this idea was 'the researcher's', it would not have existed were it not for the collaborative effort between Ronnie and the researcher.

After the insert for the Ikea furniture had been produced at the Sheffield Hallam University workshop, using a flatbed CNC router to cut the sections from Plywood (mimicking the machinery and processes available in a Fab Lab) it was shipped to Ronnie for verification. The complex process by which Ronnie could claim the money to purchase an Ikea cabinet for himself (to save the expensive shipping cost of sending one with the insert) was initiated at this time also.

Figure 12 - Insert for Ikea furniture, a 'hack' to enable bespoke storage of Vest Therapy equipment

Ronnie was very pleased with the result, and requested clarification of the process by which others might be recruited to the site (quote from Appendix A, p 28):

> *'That's awesome man! Great job! I'm looking forward to demoing this thing. Question: What's the best way to go about inviting someone to this group?"*

This led to the recruitment of Amber, who joined in on both of the project proposals (Appendix A, p 29). Amber was at the time an undergraduate design student from Michigan, USA. Cruickshank & Atkinson (2013), citing Wood (2009) recognise that 'crowds' can be made up of 'multiple individual virtuosos', and that caution should therefore be used when proclaiming the ability of a 'crowd' to creatively reflect on a design process. This research highlights the backgrounds of Ronnie (a businessman, and manager of the Cystic Life network) and Amber (an undergraduate Product Design student), since this is not considered a problem with Open Design. The researcher recorded the observations and assumptions at Amber's recruitment (Appendix A, p 29):

> *…I expect that Amber will be more comfortable in assuming the role of designer, and also facilitator- but it's interesting that Ronnie felt that Amber was the perfect fit for AIR, and out of the many, many people that Ronnie knows Amber was his choice to invite.*
>
> *I don't see the fact that Amber is a design student as a problem- since in user-innovation not everyone has the capability, or even inclination to participate. Amber is therefore an archetypal*

'lead user'- but also has the capability to be a champion, evangelist, and facilitator in AIR. It'll be interesting to see how this plays out.

So far, the two prototypes from the space were:

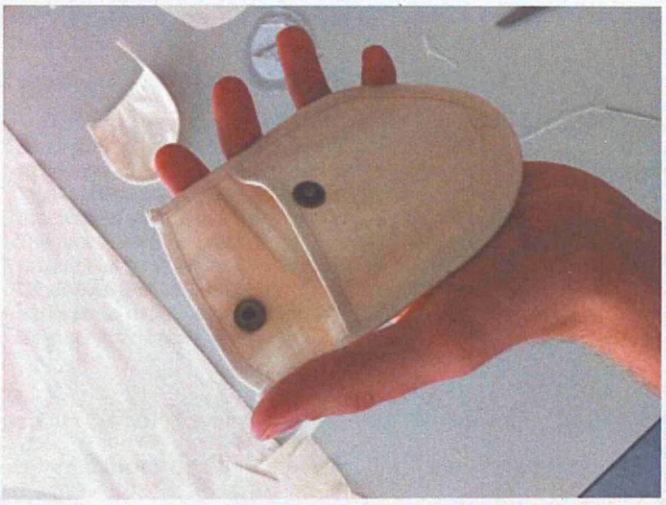
1. Medication storage / transport for clothing
2. Treatment Cabinet for Vest Therapy

The treatment cabinet received the most attention due to the fact that it was considered the most pressing need by both of the participants, and although Ronnie had not contributed sketch work or specifications, Amber posted many different ideas, and specifications of different machines to alter the design.

The work on the 'Fashion Accessories' thread in the Design Forum (this has changed emphasis to the pocket liner, suggested by Ronnie) progresses to the point of producing a prototype, which was posted to Ronnie for verification (Appendix A, p 30):

Reply by Matt Dexter on July 11, 2012 at 20:34

Ok. I have prototyped the Pocket Pocket in a rough material called Calico. It's just a basic cotton weave, but it demonstrates the potential of the design. I've attached a picture here:



Is this the type of thing that you were thinking? Is it suitable for the enzymes, or pills that you need?

▶ Reply Edit

Reply by Ronnie Sharpe on July 12, 2012 at 5:42

Wow, I think that's a GREAT start!!!

▶ Reply Message Edit

The researcher also recognised the need to continue in the recruitment effort, and as such began to use a Tumblr blog to publicise AIR, and to invite people to sign up. Tumblr had proven to be a useful tool for prototyping the 'Design Toolkit' that was sent to early participants, and by spending a small amount of money to promote a post about AIR it prompted interest from another potential participant. This participant received a toolkit, and

signed up for AIR, but did not post further. The reasons for this are not apparent, as they did not interact with any subsequent 'all user' emails sent by the researcher at future points in the case study (Appendix A, p 31).

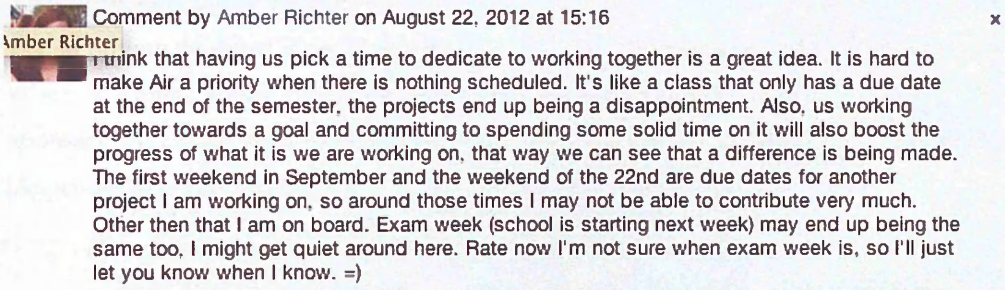
The summer period slowed the development efforts in AIR, as Amber and Ronnie had family commitments and hospital appointments. The Participatory Design Conference 2012 in Roskilde, Denmark provided the catalyst to research, and learn best practice of delivering a Future Workshop in an online space.

5.3.7. Online Future Workshop

This Action cycle falls within the Beta development phase, yet the activity itself should be considered a separate action cycle, with it's own planning, action and reflection stages. This Action Cycle is highlighted in the timeline graphic (Appendix B).

Planning:

In order to direct the work, and broaden the scope of the prototyping effort, the researcher planned a Future Workshop to be conducted in AIR (Müllert & Jungk, 1987). This was begun directly after PDC 2012, with a blog post written on the 21st August 2012. Amber replied the day after (Appendix A, p 34):


Comment by Amber Richter on August 22, 2012 at 15:16

Amber Richter

I think that having us pick a time to dedicate to working together is a great idea. It is hard to make Air a priority when there is nothing scheduled. It's like a class that only has a due date at the end of the semester, the projects end up being a disappointment. Also, us working together towards a goal and committing to spending some solid time on it will also boost the progress of what it is we are working on, that way we can see that a difference is being made. The first weekend in September and the weekend of the 22nd are due dates for another project I am working on, so around those times I may not be able to contribute very much. Other then that I am on board. Exam week (school is starting next week) may end up being the same too, I might get quiet around here. Rate now I'm not sure when exam week is, so I'll just let you know when I know. =)

The 'open access but closed door' policy (section 5.3.2, p 89) ensured that AIR conformed to the ethics regulations at the University, but prohibited the natural growth of AIR, and the community (the number of human entities in the design Thing AIR) within. The Future Workshop was intended to increase activity and the number of ideas in the Design Forum.

Action:

Ronnie and Amber were emailed about the planning for the Future Workshop (known as the 'Workshop Weekend' in AIR) on the 9th of October 2012 (Appendix A, p 37). As such, a date was set for the Workshop Weekend, and the researcher posted a blog post outlining the plan for the weekend on the 26th of October 2012. This blog post discussed the theme for the Workshop Weekend, which was *A Day In The Life*- focussing on the implications of living with cystic fibrosis for a day, including self management activities and also the opportunity to reflect on situations and interactions beyond the scope of previous enquiry.

The Future Workshop format was planned for a weekend, with the separate activities happening on different days, as per the original Future Workshop timeframe. This proved to

be too ambitious a timeframe, and when the workshop was conducted over the 27th and 28th of October 2012, by the final day none of the participants had engaged with the provocations or discussions posted by the researcher. At the end of the weekend however, both participants posted that they would prefer to extend the format considerably- with a week for each section. When conducting participatory design online, a key factor to bear in mind is that the design activity becomes more drawn-out over time (Francis & Reyes, 2012). As both participants thus far were based in America (Holly, the only UK native to participate thus far having left), this mitigated the problem of interaction across three separate time zones.

Ronnie took the lead on posting the idea that the activities should take longer – a week for each (Appendix A, p 41). He also posted in the Design Forum under the topic 'Workshop Weekend':

1. Vest tube extenders
2. Smaller lightweight compressor with high PSI output
3. Enzyme dispenser that puts out correct number of pills with single push/twist
4. Carry-on insert specifically for CF equipment/meds
5. Continue working on treatment cabinet idea.

The theme of *A Day In The Life* was not engaged with further, and as Ronnie had taken the lead in posting the list of ideas above, the researcher decided to not try and assert leadership, to see if Ronnie would direct the activity further (or, to see if Amber took over). This approach may have been too cautious, since the work on the individual concepts slowed (Appendix A, p 41):

> *However, the momentum slowed down as the project progressed, seemingly as a natural pace as the work progressed, but also because specifically Amber had University commitments to attend to. Also, my work was too 'hands off'- upon reflection, I could have done more to chivvy people along.*

Concurrent with the end of the Workshop Weekend the researcher was planning on taking the website public (section 5.3.2, p 89) - from the 'open access, closed door' to simply 'open access'; instead of people reaching a landing page for AIR and being able to go no further (view, or modify content) without an invitation code (from myself, or another member), AIR would be visible to all (although posting material still requires the visitor to create an account).

This required an amendment to the original ethics for the project, and this was granted on the 6th November 2012. The idea for opening AIR up to general access was broached by the researcher on the 1st of November in AIR, via an 'all user' email. This was during the Workshop Weekend (now extended across three weeks), and upon reflection the act of opening AIR and undergoing a recruitment drive took effort and attention of the researcher away from the design activity.

Amber's reply to the email about opening AIR was positive (Appendix A, p 42):

> *=) Sounds good. I'm still all in. I'll try to get some more stuff up here soon. Thesis 1 just sent us spinning into 50 pages of ideation (is that a real word?) by Tuesday =P So I apologize if I'm delayed at all in getting work up here (especially drawings)*

The email gave the planned 'open day' as the 15th of November, intended to give enough time to solicit feedback about the space opening up, and also to give enough time for content to be modified or deleted if members of AIR decided to.

At the end of 2012, the site was populated with ideas, and was ready to be 'taken public' (section 5.3.2, p 89)

Reflection – Workshop Weekend Cycle, and Beta Development Cycle

The period of activity immediately after the Future Workshop proved to be very busy for the researcher. As well as trying to maintain the development effort in AIR, the pressures of understanding the regulatory burden of open source medical products in meeting the MHRA[62], the change to the access permissions of AIR, and the continuing efforts to recruit more people proved detrimental to the development effort of the researcher in AIR.

The difficulty of facilitating a Participatory Design workshop is magnified when conducting the activity online, as there is often a delay in the posting. The intention of the poster can sometimes be difficult to read, and while Ronnie was taking a lead in posting the summary of ideas and the possible timeframe, this could have been incorrectly interpreted as a broader desire to lead the development effort.

Taking the site public marked the end of the beta phase, with the site 'Google searchable' and open invitations possible Ronnie posted a call on his blog. The number of active participants increased by 12. The 'beta' action cycle, during which the roles of the participants changed, was longer than the 'alpha' cycle preceding it. Amber became a strong community champion, and profiled AIR in her correspondence with others in the cystic fibrosis community. Amber also contributed a wealth of material to AIR, which enriched the discussions and design activity (Appendix A, p 43).

The site now contained 5 ideas for development, although the slight majority of these did not challenge the fundamental concept of the devices; the function of Vest Therapy was not critiqued. For the most part the ideas focussed on fitting existing devices into their lives more appropriately, rather than critiquing the device's core function. The treatment cabinet and the vest tube extenders are examples of this. However, the enzyme dispenser and the smaller compressor buck this trend. The focus at the end of this cycle is to increase the number of participants to try and achieve greater participation, to allow the collaboration to continue without the researcher's input.

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[62] The researcher met with Neil Ebenezer, the head of New and Emerging Technology at the Medicines and Healthcare Products Regulatory Agency (MHRA) on the 9th of November 2012, and remained in contact for the duration of the PhD, with Neil coming to speak as a keynote presenter at the 2nd Design 4 Health Conference here in Sheffield (July 2013). See Appendix A, p 44.

Ronnie asked me to write a guest post for his Blog mid November to invite people into AIR from the wider Cystic Life Community. This proved to be a good success, swelling the number of people signed up to the AIR community to 17. The new members were not sent toolkits (as per the ethics statement and planning (section 5.3.2, p 89)), and they joined mid way through the now slowing Future Workshop momentum.

5.3.8. Open AIR

Planning:

This 'open' cycle began with AIR changing from an 'open access' to 'open door' policy in line with the approval from the University ethics committee (section 5.3.2 p 89). The extra members were recruited via Ronnie, and his deep connection to the CysticLife community.

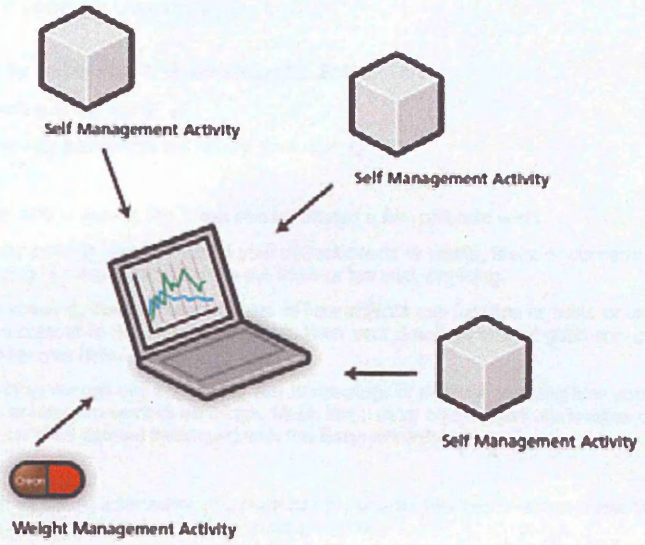
Although there had been periods of quiet in AIR, there had also been some well-paced design work for the different prototypes, with some particularly brisk work during the early stages of the Future Workshop. There were now many different ideas in the space, and sustaining development across all of these proved difficult. The researcher recognised the need to direct the design activity, and that the activity through the Future Workshop was waning. However, a timely opportunity for some external stimulus came in early December.

Martin Wildman, one of the two Consultants running the cystic fibrosis Ward at Sheffield Teaching Hospitals Trust emailed about an opportunity to develop an Enzyme dispenser as part of an NIHR research project[63]. This was timely, as the participants in the web space had suggested that a redesigned enzyme dispenser would be very beneficial to their self-management regimes. The work for the project would be twofold:

1. Develop an open-source enzyme dispenser that is capable of reliably dispensing a known quantity of enzymes per actuation (Open Design in AIR).
2. Concurrently develop a forked version ('closed source' dispenser) of this open source dispenser (once a working prototype has been produced) with data-logging electronics that will form part of the NIHR program grant (local design and engineering in Sheffield).

[63] This National Institute of Health Research (NIHR) program grant intends to study the effects of self-management equipment that has been equipped with sensors and data-loggers. These record the amount, intensity and time of different self-management activities, which are currently 'invisible' to the person living with the condition, and also to the clinical team who rely upon the testimony of their patient, which is not always accurate. The open-source enzyme dispenser forms part of this suite of 'smart' products, as the mechanics of the device were designed in AIR, and the electronics developed as a 'closed-source' addition. This shows the hybridization of open and closed source development.

The researcher blogged about the opportunity on the 20th December 2012 (Appendix A, p 47):



> *...Essentially, a system is being developed that can log different aspects of CF daily management that couldn't be previously measured- this data is then used in consultations to better help develop strategies to self-manage, or for on-the-fly feedback.*

The Open Design of the enzyme dispenser would yield prototypes that were suitable for the participants to use themselves, and also for the people involved in the wider NIHR research. In order to make the dispenser widely available, and to an audience broader than AIR, the dispenser was designed for manufacture using 3D printing.

This meant taking into account the requirements of the medium- the lack of support material on offer, the stiffness of the plastic and the laminated structure all have a bearing on how the product should be designed, or orientated on the build plate of the 3D printer[64].

The design and development of the dispenser took place in the Design Forum. The process was flawed, as the conversations can become complex over long periods of time (Appendix A, p32). The reflections in Appendix A (p 41) deal with the roles of the participants at this time. Checkland & Holwell (1998) highlight the importance of acknowledging the roles that the researcher, and the participants play in the research. As such, the lead that Ronnie, and now Amber take in directing the research through this period of development is recorded.

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[64] The MakerBot Repplicator, and other domestic 3D printers using Fused Filament Fabrication (FFF) – extruding plastic filament through a heated nozzle in layers – share a common method by which the object is built. The heated nozzle passes over a 'build plate' in the X,Y plane, extruding a thin bead of hot plastic that cools rapidly forming a solid trace. Once a layer has been extruded in the X,Y plane, the nozzle is moved 'up' the Z axis, and another layer is extruded on top of the previous one. In this way, the object is built up as a series of layers. Sometimes, if the machine settings or environmental conditions are not optimum then the object can 'de laminate', or peel apart along these layers. Similarly, the objects might shear across these layers with enough force. The machines can also only build out at a 45° angle without support material, meaning that any overhangs, or holes perpendicular to the build plate (i.e. holes in the X,Z or Y,Z planes) will end up as a 'tear drop' shape, with a round bottom and a pointed, triangular top. These are the main considerations for FFF 3D printing, without a support material.

Action:

The blog post outlined the project, and that it would fit in with our aims in the space. Amber was the first person to suggest ideas for an ideal product, taking the lead in imagining broad possibilities for the product (Appendix A, p 48):

Comment by Amber Richter on December 20, 2012 at 18:11

Are we starting broad then?

Do we have any constraints we should think about?

For anyone who is new to this ideas can be shared a few different ways.

First, just by posting text here about your current needs or wants, ideas or concerns. In brainstorming Nothing is too silly, too out there or too well, anything.

Second is drawing, You can sketch ideas of how objects can function or work, or what you want those objects to do. You don't need to think your drawings are not good enough as no one will judge you here.

Third is a thing we call use scenarios. This is drawings or pictures showing how you currently do things, or how you want to do things. Much like a story board these are images of you, or people (even stick figures) interacting with the Enzyme container.

Matt, If I'm repeating information you have already shared feel free to either delete this or let me know. Also, If I missed something please add to it!

Edit

Amber takes on the role of Champion, in defining the scope of the enquiry. The project scope could have been quite narrow, but Amber broadens out the problem space by creating a short questionnaire that other people respond to, guiding the initial scope of the enquiry.

Martin Wildman, and Sarah Thornton create profiles on AIR and contribute to discussions, especially providing feedback for the prototypes that are designed and made (Appendix A, p 53).

Shown in Appendix B is the range of prototypes that were created in the development of the enzyme dispenser. Broadly, these can be split into two different categories- Generations one through to three were based on the mechanisms taken from sweet dispensers, and the work that Amber submitted researching her own experiences of using Tic Tac boxes to store and dispense the enzymes (Appendix A, p 56). The torsion spring test and Generation 4 shows the dispenser as a functional prototype, and a proof of concept- with Version 4.3 being the dispenser that reliably dispenses a single enzyme per push.

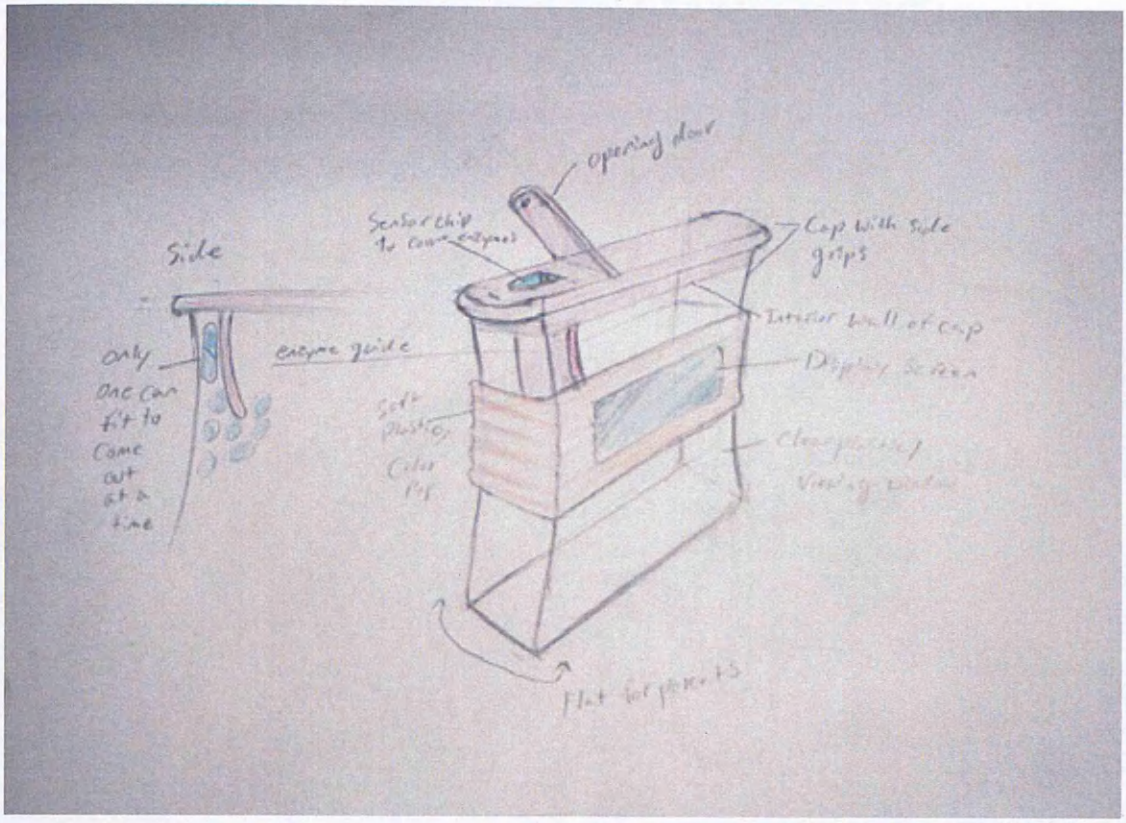


Figure 13 - A design concept from Amber, guided by their own experimentation with sweet dispensers

This research developed into an exploration that attempted to appropriate the inherent material properties of the 3D printed plastic. For instance, instead of using a metal spring as a return mechanism, exploiting the natural elasticity of the ABS, and later PLA[65] plastic to create living hinges in the designs. However the use of a 3D printed return mechanism was not feasible, since at this scale it is beyond the material tolerances for 3D printed plastic (from a MakerBot Replicator, running V7.0 firmware printing in PLA). For the 4.3 version, a small elastic band is used as a return mechanism. While not 3D printed, elastic bands are not a specialist technology and are widely available, making their inclusion appropriate for an open-source object.

[65] ABS and PLA are two popular plastics for the common 'Fused Filament Fabrication' method of 3D printing. ABS plastic has better mechanical properties for components such as gears and springs, as it is more elastic, and less brittle than PLA. ABS is a petrochemical polymer. PLA is a biologically sourced polymer, and has a harder, more glassy appearance. It is more brittle, but easier to work with than ABS. PLA does not warp or 'de-laminate' as easily as ABS, as the temperature window between PLA as a solid, and a molten liquid is smaller than ABS, which ensures a more even, and less temperamental extrusion. The researcher began using ABS, but due to the temperamental nature of the plastic, changed to the biocompatible PLA plastic to ensure reliability and consistency of manufacture.

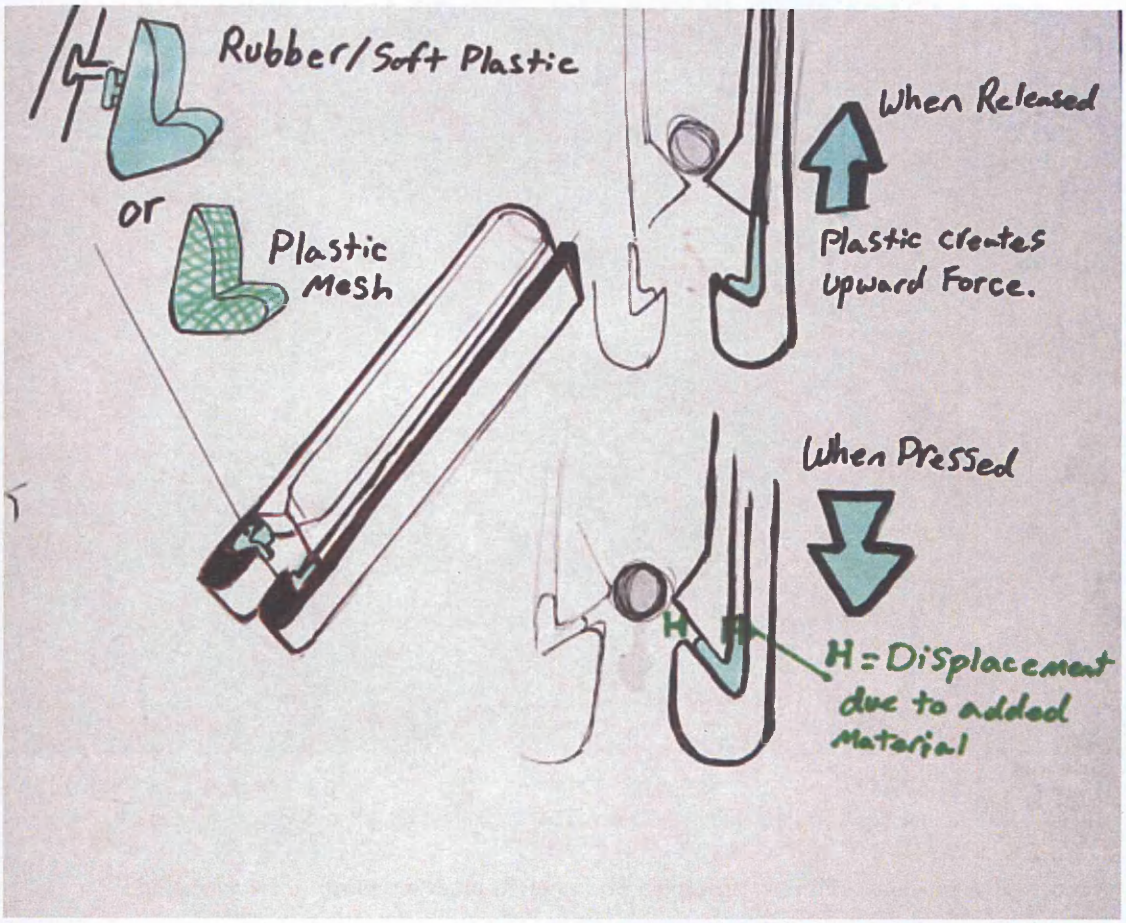


Figure 14 - A sketch from a participant for an early prototype of the enzyme dispenser

Throughout the process, Amber was keen to add to the design process, and submitted sketch work that built upon the CAD data, and the other sketches in the web space (Appendix A, p 55). CAD files for the prototypes could be attached to comments in the same way as pictures, and this was the method by which these were made available. Version control for the software in use was initially problematic, but Amber and the researcher shared knowledge of a commercial CAD program, and this shared experience and language meant that the problems were overcome.

Figure 15 - A selection of prototypes from the development of the enzyme dispenser

The device went through a rapid period of development, with discussions in AIR and even CAD files shared between participants and the researcher. The device had specifications laid down by the members of AIR, and also the people with cystic fibrosis in Sheffield (via Sarah Thornton testing some prototypes on the cystic fibrosis ward[66]). The most predominant was that it function like a 'sweetener dispenser', and participants even took it upon themselves to experiment with Tic Tac™ boxes, or use this object to base their own design concepts on.

The dispenser went through 4 major generations, and 3 major point updates (along with numerous updates for individual components) for the final prototype, that was shipped to the participants for consideration (generation number 4.3). This prototype was also uploaded to Thingiverse.com[67] to share with a broader community of makers and Open Design practitioners (Dexter, Atkinson, & Dearden, 2013).

5.3.9. Pharmaceutical Presentation | Pharmaceutical Conference Call

This Action Cycle exists as a separate cycle of activity, running concurrently with the end stages of the 'Live' cycle (Appendix B). The summary of this activity is given with in the section below, which summarises the 'Live' cycle, and the nested cycle of activity mentioned here.

[66] Testing the prototypes on the cystic fibrosis on the ward was covered by the Ward's own ethics as part of the bid for the NIHR program grant.
[67] The file cam be accessed at the following link: http://www.thingiverse.com/thing:75991
At the time of writing, it has been viewed 1,443 times and had 261 downloads.

Planning

With an enzyme dispenser prototype that dispensed a single enzyme per push, the researcher attended a conference call with a Pharmaceutical company that manufactured the most prescribed enzyme type in the UK.

The call was part of the wider NIHR bid from the cystic fibrosis ward in Sheffield, and was a good opportunity to profile the work on the enzyme dispenser – specifically the innovative use of Open Design. The researcher prepared a PowerPoint presentation, to be shared via the Internet during the call. Scheduled for the meeting was the UK manager responsible for the enzyme brand, the European manager, and the Global manager (Appendix A, p 62).

Action

During the call, a selection of the community's work was presented, and the opportunities that such an Open Design approach might bring for the Pharmaceutical company were discussed. In developing a dispenser to fit a particularly popular enzyme, AIR was effectively working as a 'niche network' around this enzyme capsule. However, the response from the company was not uniformly positive. The call had three representatives of the company involved, the UK head of the enzyme capsule, the European head, and the global head. The UK representative was vocal in her support of Open Design, and even suggested things the company could do 'We could host the site on our company servers, and run competitions to help development'. However, her colleague overseeing Europe was more cautious, and the colleague with global oversight was disinterested in perusing the idea further- it was enough for them that a new prototype had come from this research, rather than seeking to nurture and sustain this activity.

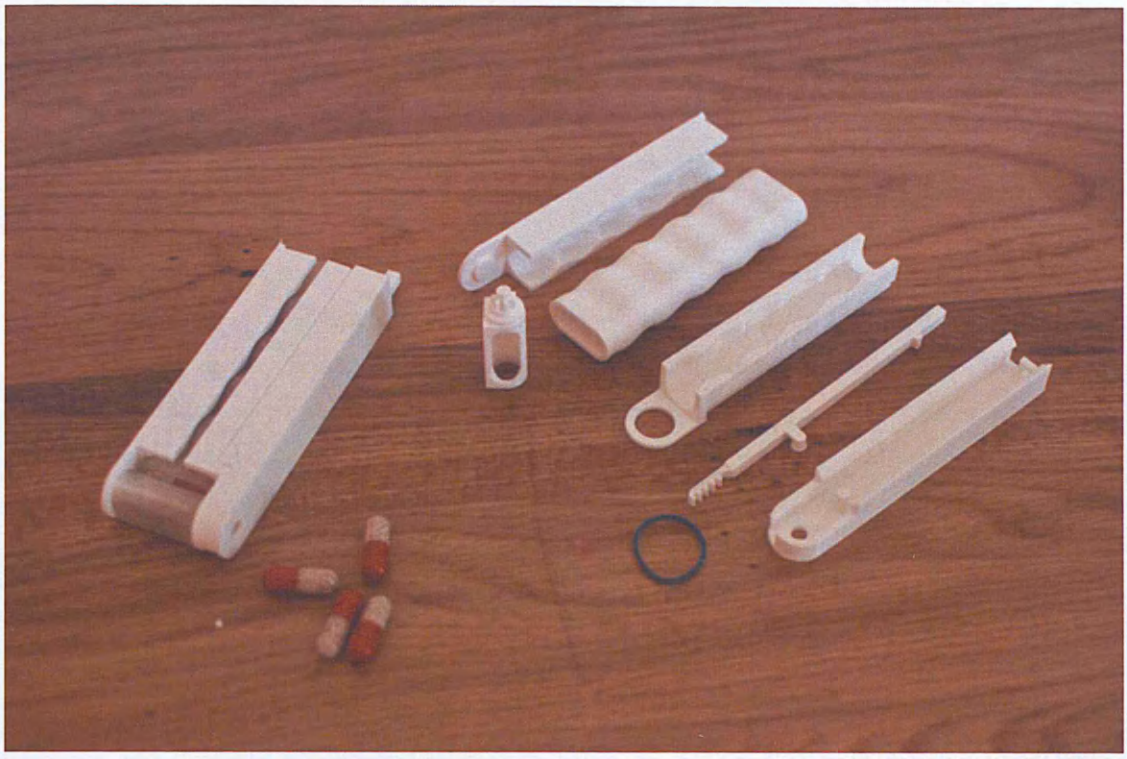


Figure 16 - Working prototype for the enzyme dispenser (4.3)

The discussion with the pharmaceutical company highlighted the need for a hypothetical business model to be visualised that could highlight the opportunities that an Open Design approach to medical product development could bring. This work was informed by a meeting and email correspondence with the Head of New and Emerging Technologies at the Medicines and Healthcare products Regulatory Agency (MHRA). The issues of regulation, and also distributed manufacturing were raised- these are two challenging areas for Open Design.

Reflection – 'Live' cycle and Pharmaceutical Conference Call

With the development of the open source enzyme dispenser (V4.3 – **Error! Reference source not found.**), and the concurrent development of sensing and data logging additions (done by a researcher external to the PhD to comply with the NIHR program grant, (section 5.3.8,.p 105) the time had come for the researcher to step outside of AIR and reflect / write up. The researcher handed over control of AIR to the biggest contributors (August 2013) – Ronnie and Amber - by making both site administrators. This gave prominent members of the community the ability to continue the development work, and also have a say in how the site is managed. Individual members retained all rights to their own posting (as they did throughout), and could post more, modify or remove content.

This marks the end of the 'open' cycle for AIR, and the cessation of the facilitated design and development work. The site remains live, but dormant- the site administrators and members have not added any new content since the handover. The design Thing represented by AIR during the period between the project's inception (January 2012), and the cessation of the

researcher's direct input (July 2013) was productive, and as shown in this chapter summary, successful in facilitating genuine participation. However, once the researcher stepped outside of the project space, AIR as a design Thing changed. The makeup of this new incarnation of AIR did not provide the infrastructure to grow the community or develop the projects further.

Fundamental to the action across all of the cycles has been the changing roles of the participants. The four main participants in this research project (including the researcher, acting in the capacity as designer) all assumed the role of designer, critic, facilitator and recruiter (at times, to a greater or lesser degree). The researcher at times struggled to facilitate the design of multiple prototypes (e.g. facilitating the production of concurrent ideas), since the constraints of the project meant that the researcher exclusively carried out the production.

From Chapter 4 we saw the foundation for the widespread implementation of Open Design, from the societal, economic and political foundations (highlighted in literature from the 1970s – section 4.4 p 53) to the Internet-enabled use of Distributed Digital Manufacturing and 'Web 2.0' technologies, facilitating media-rich discussion and interaction between diffuse participants.

This research imagines a near future, where access to Fab Labs, community workshops and DIY DDM are more commonplace; yet the constraints of the moment mean compromises for the study. At the planning stage of the project, the study was to include a MakerBot 3D printer for up to 5 participants each, shipped out to from the UK. This was not approved due to resource constraints. (section 5.3.5, p 92)

As participants joined the site, the researcher attempted to find local production facilities that the participants could use. However, no Fab Lab, Hackerspace or TechShops existed in the neighborhoods of Arizona (Ronnie, USA), Michigan (Amber, USA) or Leicestershire (Holly, UK). See section 5.3.5 (p 92) for more about the limits of Open Design in this case.

This meant that the role of producer was not enabled as part of this research- the barrier to inclusion in the production activity was not significantly lowered due to the budget constraints of the project. The production and postage method gives an approximation of the process of prototyping, but impedes 'genuine participation' (Arnstein, 1969; Hess & Pipek, 2012; Kensing & Blomberg, 1998; Luck, 2007) as the participants cannot easily effect a change during the production process. There is also a detrimental effect to the mutual learning that comes from collaborative production- although the prototypes and testing based on real-world use of Tic Tac™ boxes (for example) shows this that this was still possible to a degree.

In this design Thing, products shared via AIR (or on Thingiverse.com) were posted with a standard open source disclaimer. Essentially, they are used at the discretion of the downloader & user-manufacturer.

AIR did engage makers with regulatory experience in maker communities. The user PrintedSolid messaged the researcher on the 6th June 2013 via Thingiverse.com after seeing the listing for the dispenser (Appendix A, p 76), with concerns about the regulatory impact of the process. This message was broadly positive, and suggested that the work was timely for the current state of the regulatory environment in the Medical Technology sector (quote from Appendix A, p 76 & 77):

> *First off, I just want to let you know that personally, I think what you are doing with the enzyme dispenser is great and is probably a great potential service to CF patients…*
>
> *…it aligns closely with one of the things that regulatory bodies are really starting to push on, which is usability / human factors (supposedly the two words have different connotations in the US vs. Europe).*

However, the regulation of medical products does not support distributed manufacturing in a serious way. Standardization of the design and production of artefacts ensures safety, reliability and is a cornerstone of modern production practice. British, and international standards are used to regulate these processes, yet there are no standards existing today that could be applied to a Distributed Digital Manufacturing process.

In discussion with the British Standards Institution (BSI) models that tag CAD data with cloud-based analysis using Finite Element Analysis to assess their structural integrity were proposed (Dexter, Phillips, Atkinson & Baurley 2013). Such systems would allow for a maker to carefully assess which products would be safe to use in a certain application, and could offer an opportunity for large companies to utilize Distributed Digital Manufacturing whilst also complying with the rules for governance in producing medical products laid down by European Union and US Food & Drug Administration directives.

pgOg [illegible]

The goal in developing a community of people to participate in the design and development of any artefact is difficult to achieve (Surowiecki, 2005). Since the researcher left the site, there has been no more development of the ideas in AIR. Upon reflection, it is also apparent that the ideas to come from the future workshop are undeveloped. This suggests that the community of people living with cystic fibrosis (while enthusiastic) could not sustain the design Thing AIR, in it's second incarnation without the researcher (and access to manufacturing at the University). Shown below are the two incarnations of the design Thing AIR, and AIR':

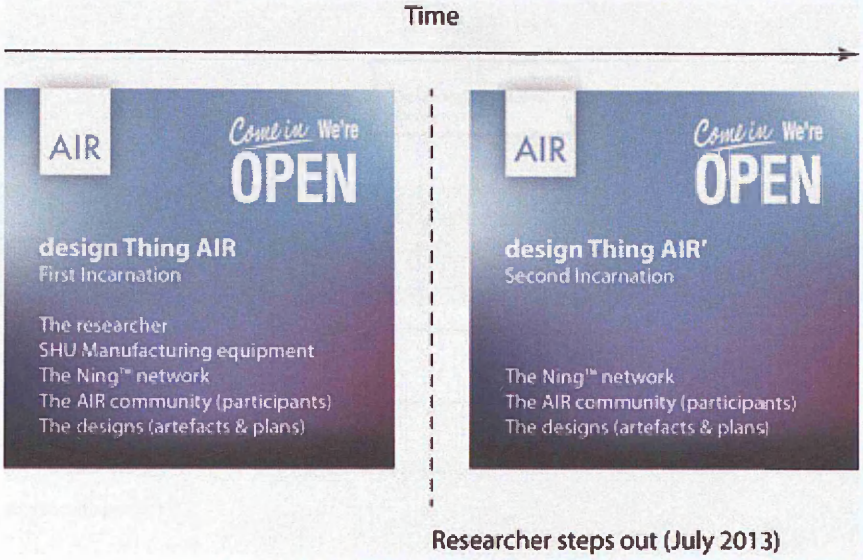


Figure 17 - The different human and non-human entities forming the two incarnations of the design Thing AIR

The change from AIR to AIR' meant loosing two key elements of the design Thing. In removing these two elements, AIR' did not continue to develop new designs, or continue development on the existing ideas. It is clear that the design Thing requires other Things in addition to itself to allow for true 'design after design' (Bjögvinsson et al., 2012) section 3.6 (p 44).

Recruitment to the site needed to be a continuous activity, concurrent with the design activity required to facilitate the development of the ideas in AIR; keeping the design practice in tension with the research activity was facilitated by the architecture underpinning AIR, as the constant recording of the activity enabled the researcher to participate in the design (Simon Bowen, Dearden, & Dexter, 2014). This continual cultivation of the community, and the constant facilitation by the researcher of the design activity highlights that while Ronnie and Amber were at both Champions and leaders of the activity, neither developed into Infrastructure upon which the continuation of the design activity might be built.

Another finding from this case study is that the prototypes to be developed in AIR did not necessarily result in 'medical products'. For instance, according to the European Union definition of what a medical product is (see section 3.5, p 40), the enzyme dispenser would not necessarily be considered a medical product (Ebenezer, 2013. pers. comm).

However, the inclusion of the electronics for recording the dispensing history on the dispenser meets the definition- specifically that the device has been created for the purpose of: '*diagnosis, prevention, monitoring, treatment or alleviation of disease*'. This means that the 'niche network' (AIR) created the prototype for a *future* iteration that was a hybrid of 'open' and 'closed' parts.

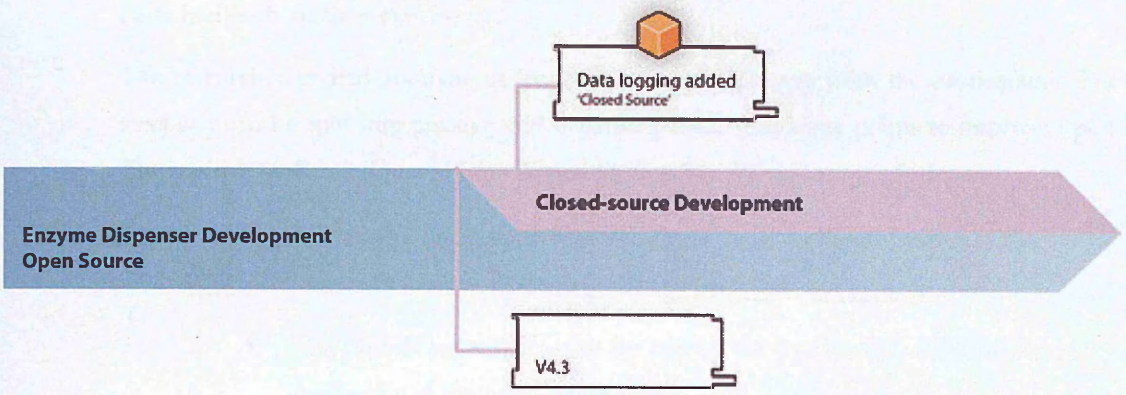


Figure 18 - Diagram from Appendix B demonstrating the simultaneous open and closed development of the enzyme dispenser

The members of AIR stand to benefit from the open source product that is created from the project, with the opportunity to download and produce a product that fulfills a need. However, the entity operating the 'niche network' has the opportunity to use the open source product as a development platform, including their own modules and modifications which they might not open source.

The issue of ethics is important here, since the entity directing (or nurturing) the 'niche network' must foster trust and goodwill amongst the community in order to maintain the development effort. This means carefully choosing what aspects of the process to 'open', and which to retain an option to keep 'closed' (Preston-Werner, 2011).

In the **Error! Reference source not found.** above, which depicts the open / closed approach to the development of the enzyme dispenser, the open source development in the 'niche network' (AIR) means that any interested third party (another person living with cystic fibrosis) could download and produce their own dispenser for their own needs- and potentially become a part of the development effort.

AIR differs from the open innovation models of medical product development mentioned in Chapter 4 in this regard. Taking the example of the Coloplast 'Innovation by You' portal, the ability to be part of the design and development process (however casually) in AIR contrasts with the 'VIP area' closed-source model in the Coloplast portal. This does not bar

the development of further products with closed-source components, since the license that the work is based upon is permissive of this activity (this is open source design, not 'Free' design- see section 4.8.2 p 6969).

5.4.1. Assumptions & Learning

This research was preceded by listing the assumptions and preconceptions of the researcher as per the theoretical framework, and research methodology (the 'F' and 'M' from Checkland & Holwell (1998). Section 5.3.1, p 88)- with Action Research here seeking to demonstrate 'lessons learnt' rather than generaliseable laws (ibid). These are expanded below from the work that was conducted in AIR, specifically relating to feedback from anonymous participants about their experience.

The researcher invited anonymous feedback about the process from the participants. The feedback can be split into positive and negative points, with some points to improve upon. The positive feedback (Quoted from Appendix A, p 81):

- *Product ideas Addressing current cystic fibrosis needs – seem more relevant to those who use the products, as they help with idea generation.*
- *New ideas are easier to expand on and weed out due to community's experience and familiarity with community specific needs.*
- *Less time is wasted trying to understand the user group and it's needs, as the design team is the user group.*
- *Design details are met sooner, such as number of enzymes that needed to be held for a day's worth of travel.*
- *Real life testing of the products. Testing the medicine cabinet has improved my correspondence with my medications.*
- *Some ideas need to be worked through more before those testing the reap the benefits, but as we work together through design and trial, each of the products will help everyone who participates in AIR.*

The feedback here demonstrates the benefits of including the users of medical products in development of new product concepts- for instance, the comments about less wasted time in development, and the increased utility [of the designs] for the user both highlight the benefits that are outlined in section 3.5 (p 40). However, the point about the medical cabinet highlights the mutual learning that is one of the hallmarks of Participatory Design (Björgvinsson, 2008; Kensing & Blomberg, 1998; Steen, 2012); the participant was empowered to critically examine their own medication and treatment regime. This means that the researcher assumption about critical reflection being hard for the participants did not mean that it did not happen.

Notably, the toolkits that were originally posted to the initial members of AIR (before opening up the space completely- i.e. during the first two action cycles) were not used. The members all responded positively to them as gifts, and in this regard they fulfilled part of their purpose- they were intended to thank the participants for their time and contributions, and make them feel appreciated. However, as a tool for to aid the 'unsticking' of knowledge (von Hippel, 2005) they did not function wholly as intended.

The feedback also covered the aspects of working in AIR that were more negative (Quoted from Appendix A, p 82):

- *I think the real struggle with these projects were deadlines and timely feedback.*
- *Some of the projects are very slow moving due to lack of involvement overall.*
- *If there is some sort of reward for involvement, or steady involvement in the projects I think people would participate more.*
- *This was hard to do with voluntary involvement, but I think if stricter deadlines were in place the projects would have a steadier pace.*
- *More group work weekends with more participants would benefit the progress of the projects.*
- *Also, once the group agrees to focus on one project, it may be beneficial to set project goals, for example week one is exploration and research, when everyone brings ideas and specifics about the project to the board. Week two can be use scenario discussion, what do we do now, and where does it need improvement? And so on through the project. This way people will have an idea of what is coming next, and how involved they will need to be.*

The pace of the projects, and the apparent lack of development for some areas are common themes in this negative feedback. The participants suggest that incentives might encourage more activity on the design projects, along with other practical steps like increasing the frequency of the Future Workshop activities. Key to this feedback is communication, amongst other participants, but also between the facilitator (the researcher) and the other collaborators. Key here is the acknowledgement that an increased headcount in AIR would lead to steadier conversations and a more thorough development effort.

This communication was hampered somewhat by the tool itself- AIR is built upon a foundation from Ning™, and while this allowed for a rapid deployment of the infrastructure the 'Design Forum' is a rather blunt instrument. Conversations are hard to follow, since comments and replies appear 'in line'; that is, not necessarily in a chronological order (for instance, the comment at the bottom isn't necessarily the most recent comment to be posted).

Some suggestions for the site's improvement were proposed (Quoted from Appendix A, p 84):

- *The Internet is a great way for those with cystic fibrosis to collaborate! It also opens the door for research to expand beyond geographical boundaries.*
- *I think a few things we could use more of in the AIR project are videos. Product testing videos are great, as well as possibly video group conferences to talk about the products that we are testing. People have a way of talking with there hands, gesturing motions while explaining how things work, or didn't work for them,, so I think incorporating video could help a lot.*

The general feedback from AIR shows that the use of Internet-enabled tools to enable increased participation was welcome- the benefits of including people from across the globe were not lost on the participants. The other point about the use of video leads back to the communication of the ideas, and the development process. Time zones, and also personal commitments are significant barriers to participation and the suggestion of video conferencing seems to suggest that the participants recognise this- suggesting a technology to mediate these barriers.

The feedback for AIR is challenging, in that it highlights the weaknesses of this implementation of Open Design, yet the facilitation of genuine participation in this case study is an endorsement of the benefit that Open Design can bring in enabling participation.

5.5. Chapter Summary

This chapter outlines the practical work completed for this PhD, drawing from the researcher's previous experience of design practice, and qualifications.

The researcher was engaged as a designer in the practical work, but this also required the research work to be held in tension. This was mitigated to a certain extent by the use of the tools that facilitated the Open Design- the Ning™ network preserves the collaborative design effort as a record that can be reflected upon equally by the researcher, or any other observer. This inherent recording of the design activity is a function of this type of Internet-enabled distributed work and means that the 'raw data' of the interactions is laid bare.

Although AIR' remains dormant, the work completed by the collaborators between February 2012 and July 2013 stands as testament to the dedication of the small but enthusiastic community of people recruited. AIR' and the prototypes that were created as part of AIR are co-owned by the collaborators, and although there is a significant portion of the researcher's time and other resources invested in these artefacts, they would not exist without the important contributions of the other participants (Appendix A, p 61).

This is a point the Pharmaceutical Company failed to grasp- the important part of AIR is not the resulting prototypes per se, but instead AIR as a niche network; as a design Thing- as an Open Design community capable of developing novel concepts. Thus AIR represents not only a novel way of enabling participation in the design process for those who find themselves excluded, but also a business opportunity for the sustained development of innovative products based upon lived experience.

Looking back on the preconceptions listed in section 5.3.3 (p 89), it is possible to review these in relation to the work in AIR (Appendix A, p 84). The scoping work (section 5.2, p 83) for this PhD proved instrumental in the forming of the preconceptions and assumptions of the researcher. For instance, in relation to the assumptions around recruitment and community building in assumption one the work demonstrated that AIR *was* an interesting and novel approach (as highlighted by the feedback – Appendix A, p 84), but that AIR needed a champion to drive the development.

Ronnie, Amber, and Holly were all champions of AIR at some point, but after the researcher stepped out and AIR became AIR', this championing of the role did not happen. This points to the work done in facilitation by the researcher, and how for a small-scale Open Design community this role proved vital.

Assumptions two and three deal with the novelty and sustenance of the design activity. AIR was certainly novel, and the product concepts proposed were similarly unique- coming as they did from the rich lived experience of the community members. The facilitation role of the researcher, and that component within the design Thing AIR is key – since AIR' has not produced novel product concepts.

Assumptions four and five discuss the necessity of high production values, and the tools that this method relies upon. In February 2012 when this list was created, the web space itself is not listed as a tool. AIR as a design Thing comprises different human and non-human entities (shown in **Error! Reference source not found.**, p 115), and one of these is the web space. Plainly the web space (Ning™ network) that AIR is built upon is a tool, as recognised in the reflection of its difficulty in use.

The Open Design methodology developed here is not generaliseable in the same way as research in the natural sciences, but stands instead as a piece of generative research to inform future design practice- it is a synthesis of the reading, scoping work, and prior experience of the researcher. It is concerned with how the world *could be*, instead of how the world *is*.

6. Discussion & Conclusion

The design of AIR was directed by the reading summarised in chapters 2-4, along with the scoping work, and previous qualifications of the researcher in Product Design. In the *Design In Health* chapter the context for the PhD is outlined; from the *Methodology* chapter, comes the raison d'être of the study- the problem of inclusion in Participatory Design for those who cannot participate. The chapter *Open Design* gives an overview of nascent Open Design methodology, with the benefits and challenges that it has the potential to bring to medical product development.

The research question of how to include people in the participatory design of medical products who are currently excluded has been approached using Open Design, with the Study chapter highlighting the process, and products that emerged as a consequence (see Appendix B).

6.1.1. Project Summary

In seeking to overcome the barriers to inclusion in the development of medical product prototypes, an Open Design methodology has been developed to enable distributed participatory design. This distribution is particularly important, as it enables the collaboration of those traditionally barred from the process to be partners in the design, development and deployment of artefacts.

Open Design comes at the intersection of different trends, and while latent within the corpus of design practice, the pervasive nature of the Internet and recent developments in Distributed Digital Manufacturing provide the ideal environment for the widespread adoption of Open Design.

6.2. Reflections from Chapter 4

The process of developing AIR and creating artefacts from the lived experience of those with cystic fibrosis meant engaging with some of the contentious issues highlighted in chapter 4 of this thesis (section 4.8, p 68). These are highlighted below.

6.2.1. Intellectual Property, 'Copyleft' and Creative Commons

In sections 4.8.1, 4.8.2, and 4.8.3 the issue of ownership of ideas is discussed. In applying a license to a work a designer is able to maintain a level of control over the use of that work, with permissive licenses allowing for commercial derivatives; and Copyleft (or other 'Free' licenses) prioritising the freedom of access to software over enabling commercial use. As we have seen in discussions of ownership from Pettis (2011) and Sedle (2012) (sections 4.8.1, and 4.8.7) the enforcement of ownership through litigation can be a futile exercise.

AIR, and the files shared through Thingiverse.com for the enzyme dispenser are licensed under a Creative Commons License to ensure attribution of the intellectual property. Initially, the enzyme dispenser files were licensed under a non-commercial license on

Thingiverse.com, although to ensure that the files are as permissive as possible (and therefore more open), the non-commercial requirement was lifted.

6.2.2. Professional Identity

The roles taken by the participants during the case study are reflected upon in sections 5.3.5 - 5.3.9 (p 92 – p 110). These sections describe the *Planning*, *Action* and *Reflection* cycles of the case study. The participants Holly, Ronnie and Amber all changed roles at points, sometimes acting as provocateur, sometimes as designer and sometimes as champion of the project. Holly and Amber both challenged the role of the designer, as both self-identified as being 'creative'.

Amber is an exemplar of this, by contributing designerly outputs during AIR and taking the lead in the execution of the design work, without being employed as a designer. However, Amber's schooling in design, and Holly's passion for design might be seen as a detriment to the Open Design method as per Cruickshank & Atkinson's (2013) critique (discussed in 5.3.6). Amber and Holly (as those self-identifying as creative people), as with Ronnie (and the others) were enabled as Lead Users (von Hippel, 1986) to develop products based on their lived experience- leading back to the historical context of Open Design, and the call for technology and tools that enable full creative freedom for the widest possible number of people, to the benefit of mankind – section 4.4, p 53 (Gabor, 1972; Illich, 2001; Schumacher, 2011).

6.3. Open Medical Products Methodology

This PhD study has shown that Open Design does have a contribution to make to medical product development, but this should not be viewed as a grand utopian vision of a future world- rather, a practical tool to complement an existing design and development methodology. It is the position of the researcher that Open Design has a pragmatic contribution to make, one that is not anti business; instead opening up new avenues for business development. This is highlighted by the work conducted in AIR, as the genuine participation fostered amongst the community allowed for practical solutions to identified needs- where solutions did not previously exist.

AIR can be plotted on the axes of Troxler's (2011) diagram describing the 'libraries of peer production' (section 4.5, p 56).

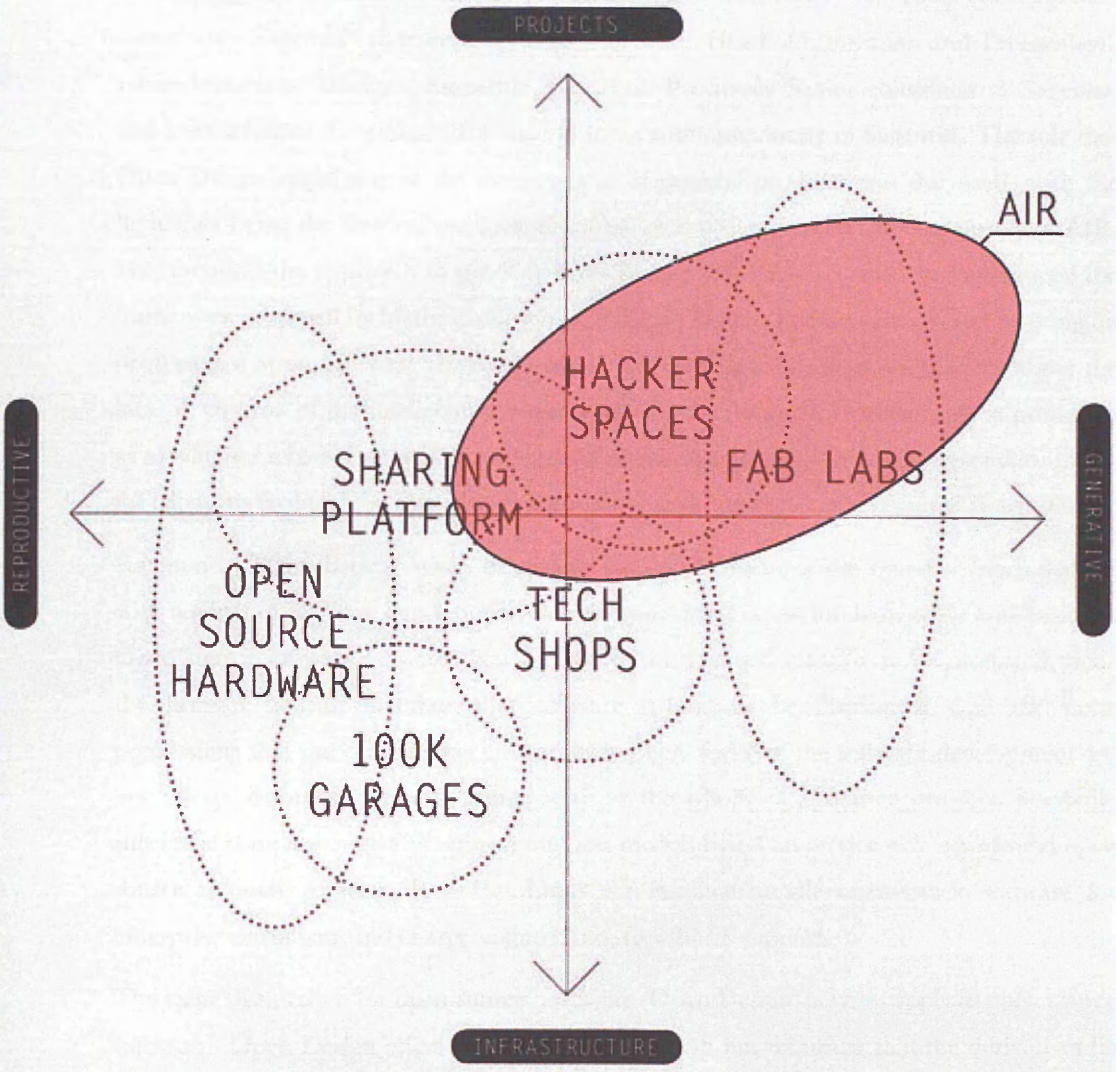


Figure 19 - AIR plotted on Troxler's (2011) 'Libraries of Peer Production' diagram

AIR straddles the axis between 'projects and infrastructure', and 'reproductive or generative', mostly existing in the quadrant between 'projects' and 'generative'. This best describes the projects found in the Design Forum of AIR, since these are original works. However, there is still an element of reproduction- the designs are available as an informal library for visitors or other community members to download. This storage of reproducible ideas is not as formal as Thingiverse.com (for instance) hence AIR not covering more of this area in the diagram above.

AIR also provided infrastructure for the production of ideas meaning that the plotted area above incorporates this. Overall though, AIR is predominantly about the generative production of novel projects.

6.3.1. A pragmatic approach

The researcher recognised the need to discuss the pragmatic viability of an Open Design methodology for medical product development, and as such visited the product development consultancy Sagentia[68] to interview Gregory Berman (Head of Innovation and Technology), Libby Wingham (Director, Empathic Mind Ltd. Previously Senior consultant at Sagentia) and Lucy Mullace (Consultant at Oakland Innovation, previously of Sagentia). The role that Open Design could play in the development of medical products was discussed- with the highlights being the medical products that had been prototyped by the community in AIR. We discussed the approach to product development that Sagentia uses, and referenced the framework proposed by Shah, Robinson, & AlShawi (2009). The benefits offered by using an open source approach were cautiously welcomed, although the client reservations about the lack of 'control' of the intellectual property remained a concern. However, when prompted as to whether a consultancy such as Sagentia might offer to build Open Design environments for clients to facilitate the sort of work carried out in this research, the response was positive.

Raymond (2001c) is clear when discussing the development of the moniker 'open source' with regards to software development that the movement is not fundamentally anti-business. Open source software licences allow for hybrid open/closed software to be produced, since the licenses do not mandate that software derivatives be distributed with the same permissions that the original was created with. Such 'forks' of the software development are not always embraced with the same verve as the wholly open-source projects. Similarly, successful companies have developed business models based on service delivery around open source software projects- Red Hat Linux for instance bundle open-source software for enterprise customers, and charge maintenance fees for IT support.

The same distinctions for open-source hardware (Open Design) licenses apply as open source software - Open Design offers the same pragmatism in not requiring that the derivatives be shared with the same licenses that are applied; the community of people will decide whether the 'forked' design is appropriate or worthy of continued support. It will be embraced or rejected based on how the producer treats the community of makers who form the niche network around the product (or product line). This is because Open Design is not 'Free' Design- the derivatives of an idea are not necessarily shared with a 'share alike' requirement (section 4.8.2, p 69).

This pragmatism carries through from Leadbeater (2009), with the idea of a hybrid open/closed system ensuring the most appropriate artefacts are created. Hulme (2011) reiterated this idea when he profiled OpenIDEO at the Intersections 2011 conference; when asked which entity produced the 'best' designs ('open' or 'closed' IDEO) Hulme responded that in his opinion the best results came from a hybrid approach between the open and closed paradigms.

[68] Sagentia is a global product design and development consultancy headquartered here in the UK. Sagentia works across different sectors, with a particular expertise in medical product development, aided by the cross-disciplinary nature of their work.

In this regard, the research conducted here empowers people affected by a situation to be a part of the development of artefacts to mitigate / manage their lived experience. This empowerment comes with collaboration moving beyond consultation (Arnstein, 1969; Sanders & Stappers, 2008; Simonsen & Robertson, 2012).

The methodology presented in this thesis is pragmatic in the sense that it does not seek to fundamentally refute the established model of design and development of medical product prototypes, instead to lower the barriers to inclusion for the prospective collaborators in the process. This has benefits for the people who live with chronic conditions, as they are empowered to participate (Arnstein, 1969; Simonsen & Robertson, 2012); the manufacturers of medical products gain access to potentially untapped sources of research and development (access to *Lead Users*) (Cruickshank & Atkinson, 2013; von Hippel, 1986, 2005); and the platform that Open Design creates has the potential to extend, or redefine the project boundaries, potentially meaning greater markets for the manufacturer and greater scope of artefacts for the participants with chronic conditions[69] (Bjögvinsson et al., 2012; Fischer & Scharff, 2000; Press, 2011).

[69] Extending the design activity beyond the original scope of the designers / project leaders is discussed in Bjögvinsson et. Al. in the context of *Design Thinging* the Thing being a socio-material construct spanning the artefacts created, and the space in which the deign activity resides. Section 3.6, p 39.

This thesis does not seek to present a utopian vision of Open Design. As such, it is prudent to highlight some theoretical business models that might be adopted in conducting business in a hybrid 'open source' / 'closed source' manner (Leadbeater, 2009). From the development of the enzyme dispenser in AIR, and following the conference call with the Pharmaceutical Company (section 5.3.9, p 110) a business model based on the research here was developed.

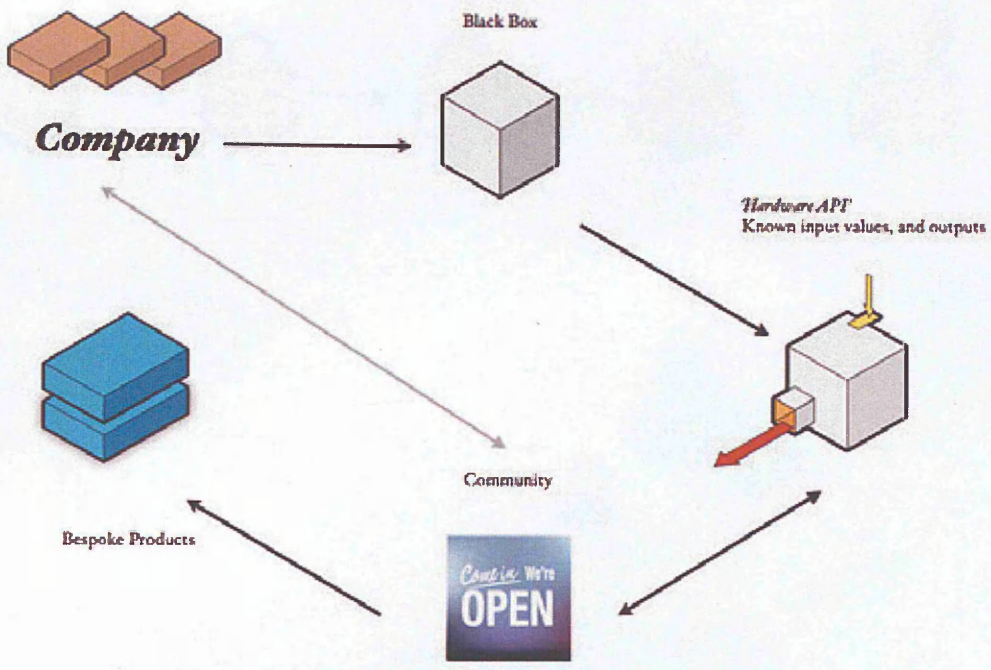


Figure 20 - Example business model for a company wishing to engage a community

In this example, the company produces a range of products with an enabling technology, with this enabling technology made available as a component alongside the existing product range. This component is a 'Black Box' (Berry, 2004; Winner, 1993), which is not open source itself, but has a 'hardware API'- an interface of known input and output values that mean the device performs in an expected manner. This enabling technology is embedded in the designs of the community, whose activity is nurtured by the company (hence the double-ended arrow). The community creates bespoke products tailored to individual needs, which gives the company rich access to a Lead User perspective (von Hippel, 2005).

Some open source proponents are against the use of 'Black Box' components (Torrone, 2012; Berry, 2004) since they are not 'Free', but there have been Open Design communities that have used closed-source components successfully (Raasch et al., 2009). Mixing open and closed source components is known as an 'open parts' strategy (ibid), made possible by the use of a suitably permissive licence.

'Free' software / hardware licenses require that any derivative work be licensed with the same terms, which is 'anti business' (Pearson, 2000). Open source licenses do not necessarily make such a requirement (although they can) and are more acceptable to an 'open parts' strategy for business.

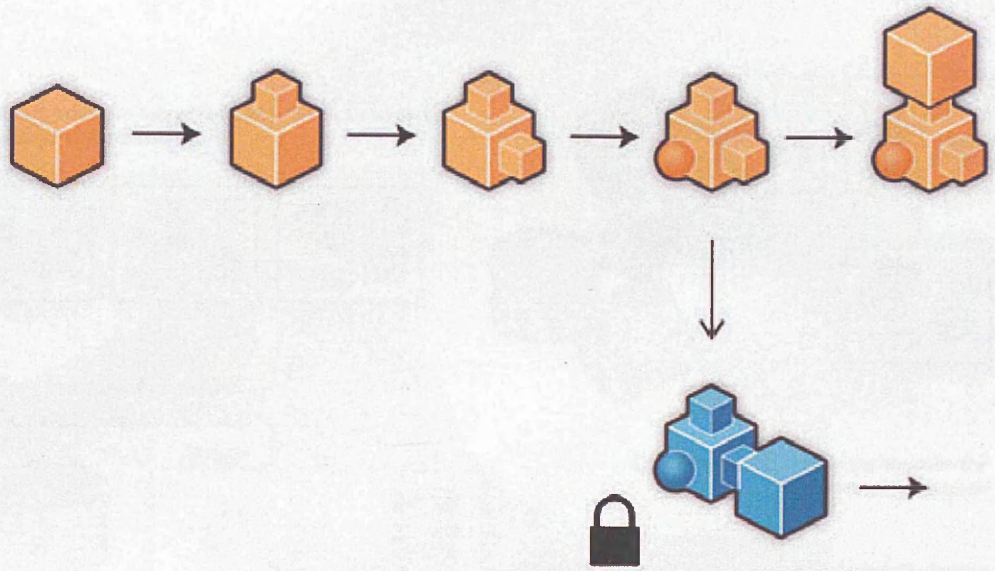


Figure 21 - Closed source development informed by an open source approach. A proprietary derivative.

The 'open parts' strategy is not the only method by which Open Design might be leveraged in the collaborative production of products. The company might integrate portions of the open source development into their traditional R&D approaches and 'fork' the development of an open source product with their own closed source variant.

This approach ensures that the community has access to the open source development process and assets, while at the same time providing the company with the opportunity to produce it's own 'value added' products for retail. Assuming that the company deals ethically with the community (by adhering to the customs of open source culture (Raymond 2001b; Torrone 2012)) the closed source variants will not stymie the concurrent open source design and development.

The development of the enzyme dispenser followed this development path, with a concurrent 'closed source' data-logging module developed for use in the NIHR program grant (section 5.3.8, p 105).

In both of these business models, there is an assumed quality standard that is adhered to, and that the company can rely upon the different design processes and outputs that the community produces; particularly if the company is relying upon the community members to manufacture their own equipment via paid download of the plans (Distributed Digital Manufacturing). This standardisation would require that the community members have some way of verifying the designs that are produced. (Dexter, Phillips, Atkinson & Baurley 2013) propose cloud-based geometric and Finite Element Analysis of digital CAD data, which can be quantifiably assessed for its adherence to certain standards.

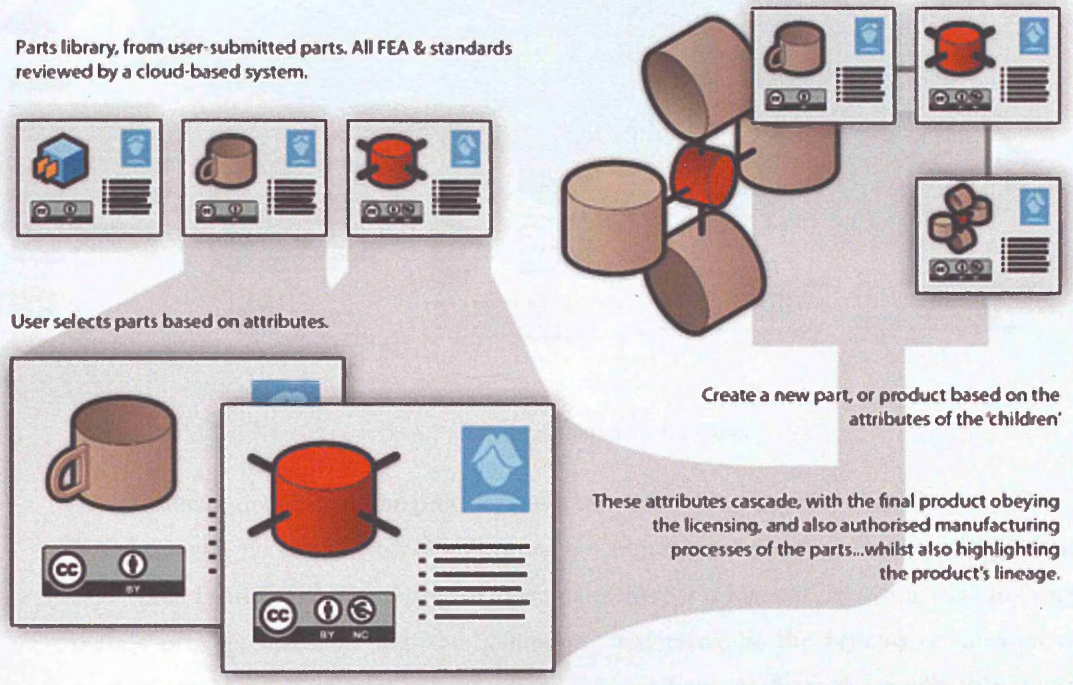


Figure 22 - Proposed standardisation and licensing model for Open Design (Dexter, Phillips, Atkinson & Baurley (2013)

Such a system would allow for complex products to have a lineage, with licenses and required manufacturing processes (in order to be 'standards compliant') cascading through the lineage. However, this infrastructure does not yet exist and at the current time artefacts are being released with disclaimers and without warranty. This is not conducive to proper medical product development, and as such illustrates one of the main points for further work in Open Design.

6.3.3. Prototype Open Design roadmap

As part of the Fairphone 'Design Bootcamp' (Mier, 2013) the researcher collaborated with Casper Jorna[70] on a prototype roadmap for an Open Source, modular approach to smartphone hardware for Fairphone.

[70] Manager Business Development & Sustainability at Vodafone

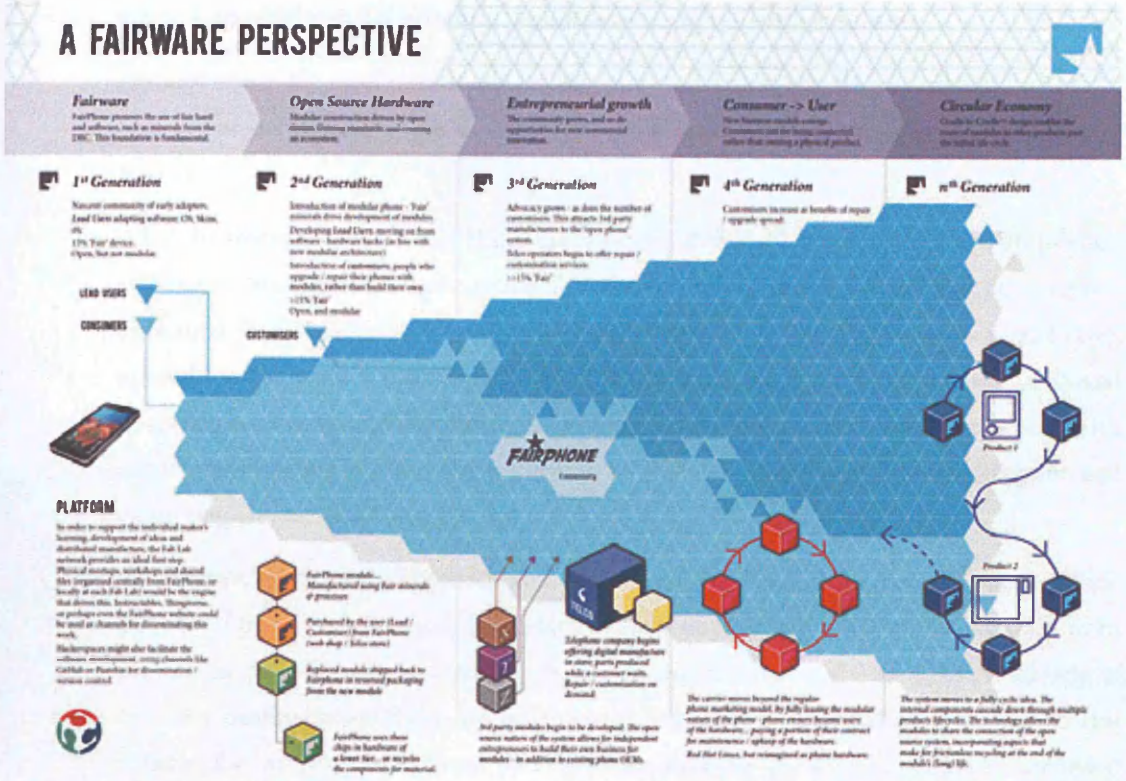


Figure 23 - 'A Fairware Perspective'. Prototype roadmap for Fairphone

This roadmap draws upon the previous business model of 'open parts' (Raasch et al., 2009), but also highlights the benefits of cultivating a community of people and empowering them to become Lead Users. The system of 'open parts' here is pragmatic, in that it seeks to bring mobile network operators into the community and recognise the benefits of third party module producers in the overall ecosystem (this roadmap predates the public releases of Google's project ARA (Eremenko, 2013), and PhoneBloks (Hakkens, 2013)). The environmental and economic benefits of the roadmap align with the historic contributions to the nascent field of Open Design (Gabor, 1972; Illich, 2001; Schumacher, 2011) (section 4.4 p 53), in that the components used in the products are modular, and could be incorporated in new generations of future products, rather than becoming waste.

A key assumption in this roadmap is that the overall number of passive consumers would decrease, as access to tools and processes (retail, design, production) increased, or became more accessible. This would lead to a third class of customer beyond 'consumer' and 'lead user' – identified above as 'customiser'. This views the customer base as a continuum from individuals likely to propose their own bespoke electronics, software, or even prototype hardware (Lead Users), individuals who might 3D print another enclosure, or install a different operating system written by someone else (customiser), and an individual who uses the phone as found at the point of sale (consumer). Also assumed is the continual growth of the consumer base for Fairphone, and the scalability of the enabling initiatives highlighted along the bottom of the image.

6.3.4. A *physical* Red Hat – Service, Maintenance, and Quality Assurance

Perhaps one of the most radical shifts in thinking would be to emulate an established FLOSS business model by one of the most successful companies built upon open source software- Red Hat, Inc.

All of the software used by Red Hat is open-source. Red Hat has even purchased proprietary software companies and 'open-sourced' the code, releasing the foundations to everyone (including those traditionally seen to be competitors). The Red Hat business model relies upon the stability of the open source code, with the revenues not coming from sales of boxed operating systems or software distributions; rather Red Hat provides quality assurance on it's Linux distributions to enterprise clients, as well as providing customer support and consulting on enterprise installations.

A corporate entity might approach Red Hat for software to underpin a core aspect of their business. Once commissioned, Red Hat compiles appropriate open source software from projects in the wild- this has the benefit that the open source software in use is already of excellent quality (having been subject to continuous peer-review) and up-to-date. Red Hat vouches for the bespoke software package created for the client corporation by employing highly competent software engineers (who themselves contribute to open source projects) who provide this quality assurance.

Therefore, Red Hat is able to charge for the consultation (including specification, design and delivery) of the needs, the installation of the software, and then provide technical or customer support to the client after the fact. The fact that Red Hat does not 'own' the code is inconsequential – they instead tailor software for clients that are unable (or for whom it is not cost-effective) to do so. Crucially this is not unethical to the community of open source developers, as those developers' contributions are recorded in the software code, and the community benefits from the developments to the open source projects from Red Hat – because the work conducted by Red Hat itself is open source and fed back into those same projects.

The physical Red Hat

A company for whom a physical artefact is their core offering might find the above description of doing business alien. Producing an artefact and charging an amount to cover costs of production, with an added amount of profit to what the market will bear is fundamental to our capitalist economy. Turning that product 'loose' requires the fundamental aspect of 'ownership' to be rethought- or perhaps grasped less tightly.

Customers are willing to pay for open-source hardware to be made by an entity that represents *Quality Assurance*. As an example, Ronen Kadushin has produced and released many open-source pieces of furniture, including the *Italic Bookshelf*. The plans for this bookshelf are readily available from Kadushin's own website[71], and depending on the choice

[71] See more at: http://www.ronen-kadushin.com/index.php/open-design/italic-shelf/

of materials could be produced for around £50 (assuming access to a CNC router through a community maker space or Fab Lab). However, an *Italic Bookcase* made by Kadushin himself is worth more- much more in fact. At an auction on the 26th September 2009 a bookcase was sold at a Phillips auction for £8,125[72].

Kadushin (2012) accounts for this difference because his name was on the shelf, and as part of the sale a certificate of authenticity was included. The importance of this quality assurance is a central aspect of a successful Open Design business strategy.

As part of this research, the researcher purchased an Arduino mini electronics kit. There were numerous copycat boards to choose from with seemingly identical technical specifications (and lower prices), yet the choice to purchase an original Arduino board was already made by the researcher- the official board came well packaged, with stickers and a very high build quality. Such additional touches are key in differentiating a quality-assured open source *product*.

The production vales of open source hardware matter because the artefact is tangible in a way that software is not. The quality of the finish, the robustness of the *thing* and it's provenance matter (the Arduino board is made in Italy; the *Italic Bookshelf* by Kadushin himself). Similarly, when the researcher purchased the board the access to a community of makers and other Arduino users became significantly more useful. Of course, it would be possible to develop open source hardware based on a copycat board and use the Arduino forums for assistance, but technical support is reserved for Arduino hardware only.

This quality assurance aspect becomes the crux of *'the physical Red Hat'* – customers have demonstrated a willingness to pay for the assured (or assumed) quality of an artefact by a trusted producer. This trust could come from the producer's demonstrated prowess and mastery in producing high-quality artefacts (that happen to be open source). Or, the trust might come from their ethical dealing with their community, including choices in manufacture that show them to be principled actors (like Arduino securing manufacturing jobs in Italy, rather than outsourcing production).

In order to truly be *'the physical Red Hat'* a producer would incorporate multiple Open Design projects and fold them into their own product offering- which itself would be open source.

This is the key difference between the 'open parts' strategy described above, as it represents a complete shift in the notion of ownership. In this regard, it is the most radical of the ideas discussed in this thesis, however these ideas are not new. The shift from 'software as proprietary product' to 'software for service offering' was radical too (and is still for some) before Red Hat Inc. In the same way, Open Design could pave the way for companies that combine disparate artefacts, themselves well-conceived and of high quality (possibly vouched for by the standards procedures outlined above) into quality products that form the basis of a

[72] See more at: http://www.phillips.com/detail/RONEN-KADUSHIN/UK000209/90

consultation, instillation and support business model... underpinned by *trustworthy quality assurance.*

6.4. Conclusion

The knowledge created during this PhD as a synthesis of the reading and practical work (AIR) is summarised here in this thesis; being research in that knowledge was the goal of the activity (Archer, 1995), and that the process by which this was achieved was planned and conducted as to be *recoverable* by another researcher (Checkland & Holwell, 1998)- by presenting a record of the activity (AIR – online) and the researcher's reflections (Reflective Log – offline; Appendix A).

The research question for this PhD (section 1.1.2, p 8) asked:

> *How can people who are barred from Participatory Design through living with a chronic condition be included in the design and development of medical product prototypes?*

To answer this question, the context of design in health was investigated (section 2, p 13). This sets the tone for the research, and informs the way that design as research through practitioner activity (Archer, 1995; Frayling, 1993) can be part of the research milieu of health research. From this perspective (design in health), the appropriate theory, epistemology, and methodology (of research) are outlined with respect to participation in design, and particularly participation in medical product design (3, p 30). The methodology of practice is outlined in Open Design, as well as highlighting the current discussions and definitions of the nascent paradigm (4, p 47). Finally, in chapter 5 (p 81) the study is detailed in which the practical outworkings of 'doing' Open Design with a community of people are outlined.

Genuine participation was facilitated for the collaborators who worked in AIR (section 5.3.9, p 110), since the feedback of the people who took part (a requirement for the reflection highlighted in Checkland & Holwell (1998)) detail this. The ability to dictate the direction of the development, and to have a say in the prototyping work at any stage (compared with the framework highlighted in Shah et al., (2009)). Open Design does appear to facilitate the participation of those who could not previously participate in a Participatory Design process.

6.5. The Social Expert

In this thesis, the roles of the participants are recorded and reflected upon, with Amber, Ronnie and Holly all assuming different mantles during the work; designer, facilitator, researcher, and lived experience expert.

What of the researcher? What of the designer in this work?

Open Design has a profound impact on the role and work of the designer, even those who are used to working in a user-centred, or participatory framework. The democratisation of the means of production and tools of design mean that we must re-evaluate what it means to be a professional designer in this context.

Sennett (2009) discusses the 'social expert'- the outward-facing nature of expertise that encompasses the mentoring of others, the adherence to transparent (not esoteric) values and ethics, and the 'treating of others as whole persons in time' (ibid) are marks of the social expert.

These facets of social expertise sum up the Open Design work here conducted with the AIR community. The mentoring of others, the co-production of artefacts leading to critical self-reflection of the participants, empowerment- the sharing of plans, blueprints, and the creative process in an open and lay-readable format, and the overt communication of the intentions and motivations of the researcher all fit the descriptor: The social expert.

I am a social expert.

Designers who create, or work in Open Design platforms or spaces should recognise the importance of what is required of them, and how the role is *more than* that of a facilitator; more than an observer; instead a complex combination of these facets with the additional mentoring and enablement of a Master (to borrow from Sennett's analogy of the craft workshop environment).

The designer therefore has a commitment to high quality designerly work in a collaborative context, with shared knowledge and transparent goals.

The production value that designers bring to even the early stages of the design process cannot be underestimated, and with Open Design the opportunities to share this process is increased. Here the social expert is at their most valuable – sharing knowledge to improve designs and spread good work (for good work's sake), not segregating their expertise and storing up their expertise in silos.

6.6. Recommendations

The work for this thesis highlights changes in the practice of design. In demonstrating the efficacy of Open Design, with the research into other Open Design (and open source) projects the challenge to the standard order of business for design is laid bare. 3D printing, and other internet-enabled tools in community settings are being developed even as this thesis is written, with advances in techniques and tumbling costs combining with ever lower cognitive barriers to entry making the breakthroughs available to more people.

This acceleration in the democratisation of the means of production poses a challenge and a significant opportunity to design, to design education, to the NHS, and to patient / advocacy groups in general.

6.6.1. Design

In section 6.2.2 (p124) I outline the different roles that the participants took throughout the project, and how the definitions shifted as the design activities played out in AIR. In the previous section (6.5) I discuss the Social Expert- designers, and in particular

product/industrial designers and design managers, must heed the developments in distributed manufacture and Open Design- in the same way graphic design had to heed the democratisation of the tools for layout and print. If we do not, we risk alienation from a growing population of makers and lay-designers- potential customers, clients, *collaborators,* and *fellows* all.

6.6.2. Design Education

Cross (2007) discusses the requirement to change the model of design education. Central to this is the thesis that design forms a third branch of human knowledge distinct from the Sciences (concerned with how the world *is*), and the Arts & Humanities (concerned with humans *in* the world). Design for Cross is concerned with how the world *could be* – it is fundamentally generative in nature.

This is not to say that design does not borrow heavily from the sciences, or indeed the humanities (see section 3, p30). Rather, that the abductive reasoning predominantly used in design sets the work done by designers as distinct from the Sciences, and the Humanities.

For Dorst (2011) the main mode of reasoning that designers use in these open-ended conceptual scenarios is Abductive-2 reasoning. The premise of this is that the working principle and the 'thing' are unknown in the problem, only the value that is required at the end. The concurrent development of these is key, and Cross (2007) uses interviews with 'expert' designers to highlight this process in action.

The challenge to design education comes in not only teaching this designerly way of thinking, but also in responding to Open Design and the democratisation of high-quality production methods. This will be different depending on the level of education being delivered.

Undergraduate

At undergraduate level, there is little room for manoeuvre for module choices. As the researcher has experienced first hand there is little enough time to develop the skills required to practice design professionally. However, this should not be seen as an unimpeachable barrier to taught Open Design.

For instance, the development of community maker spaces within the University should be explored, not least for cross-discipline collaboration but also for engagement with the wider public. Here, design students could be encouraged to perform the role of the design tutor and therefore gaining experience sharing their knowledge… therefore starting their development into social experts.

At the same time, undergraduate designers should be encouraged to share their ideas with their peers, but also with the wider public. At some levels this is already done – certainly at Sheffield Hallam University it is common practice to run exercises where design students come up with ideas and are then required to 'swap' with other members.

This exercise could be modified, with the design students posting their ideas to a board, with some markup and simple documentation explaining the intricacies of the design. Just as with a FLOSS or Open Design development process some ideas will receive development and others will not. In this instance, the undergraduate designers will need to deal with their ego, and their fledgling professional identity. Will 'theirs' be the idea that gets developed? What will they bring to the development process? Working through these issues, and being exposed to them early in their careers will prepare design students for the realities of a world in which anyone is able to produce their own objects in a previously unimagined rage of materials and processes.

Postgraduate

The project structure of postgraduate design degrees allows for more flexibility in the conception of an Open Design project. The requirement that the degree demonstrates a level of research also allows for the designer to critically reflect on his or her own design practice to a greater extent.

In this setting, the social expertise of the designer can be teased out more; *how* might the instruction and tutelage of lay designers be facilitated? What products or scenarios might benefit from the application of Open Design? How are complex barriers to Open Design to be overcome?

Questions such as these require a rigorous approach befitting a Masters or PhD. The nature of Open Design requires that the projects be collaborative to an extent- it might be that some future research is able to take an anthropological approach to observation of a large and successful community of Open Designers[73], for instance. Even if the project were fully 'hands off' with regard to other lay designers, the design student themselves would be required to work in an inter-disciplinary way to answer such broad questions.

Facilitating Open Design Education

The challenge to the University is clear, in that the adequate provision of community focussed workshops is a requirement for the coming changes to design. Some forward-thinking Universities already leverage the benefits of an on-site Fab Lab, with Mälmo University's *Fabriken* and the Aalto University Fab Lab being excellent examples.

In parallel to the physical requirements is a recognition of the changes underway that are wider to Open Design's challenge to design practice. The democratisation of traditional methods challenge a number of sectors – from Keen (2008) lamenting the rise of the blogger and the waning of the professional journalist, to the increasing adoption of Massively Open Online Courses (MOOCs) in education.

A forward-thinking institution will recognise these requirements and situational changes and respond to them. The old method of training students for well-defined jobs in design is

[73] This PhD was not able to consist of this approach; as such a community of Open Design for medical products does not currently exist.

changing fast, and with the increasing uptake of Open Design we as design educators do students a disservice in not adequately preparing them for a rapidly changing sector.

6.6.3. Health Sector & Patient Advocacy

The United Kingdom's National Health Service does not need to be convinced (on the face of it) that greater 'Patient and Public Involvement' (PPI) is key to the development and delivery of increasingly effective health services.

However, it is the researcher's own experience that PPI efforts deployed by the NHS can be very low on Arnstein's (1969) Ladder of Citizen Participation. That is to say, these PPI efforts can be consultatory and not present the participants with a clear mechanism for having an impact on an initiative.

The fostering of Open Design in a health setting, perhaps even with the open-source development of a clinical scenario or service could be a powerful method of engaging with people in a meaningful and empowering way. The development tools and methodologies outlined in this thesis would allow for deep participation in the design process whilst also facilitating the type of in-depth communication about the development process that is so hard to communicate presently (by 'participants' in PPI sessions being removed from the decision making process).

Of course, such inclusion of people in a profound manner in the development of health services might seem to be at odds with such a notoriously risk-averse institution as the UK NHS.

Design is currently used in NHS settings to great effect. In chapter 2 (p 13) the use of design in health is laid out, with both challenges and opportunities. The great benefit to the health sector is deep and meaningful participation with those who depend on the service the most. This rich seam of lived experience could form part of a sustained and on-going development process whereby an Open Design approach informs the development of services and client (patient) facing attributes, while also allowing for staff-led innovations to be folded into the process.

This moves beyond the EBCD (section 2.6, p 22) in use today, by empowering those within the NHS and those without to have a meaningful impact on the provision of the nation's health.

This would require a change in attitude to the risk posed by the delivery of healthcare. A risk-averse institution finds innovation more difficult to generate and implement; the mitigation and management of risk to life is a core requirement of the NHS, but this need not preclude the inclusion of designerly spaces within the NHS as a whole to tray and tame some of the Wicked Problems lurking within. A Fab Lab in a hospital is a novel idea, but there should certainly be a 'designer on call', within an Open Design framework facilitating distributed design. This would allow infirm patients to post feedback and perhaps vent

frustration- however instead of this being recorded negatively as part of a PPI exercise, in an Open Design context this negative feedback could be the stimulus for a spontaneous and positive redesign of how a service is delivered.

Working in such an open manner also holds the institution to account. We saw from the description of the social expert that institutions that hold themselves to scrutiny against values laid out plainly have more integrity; and for an institution such as the NHS that has faced ignominious scandals from seemingly inscrutable decisions and actors such a radically open approach to it's core business of health service provision could certainly be revolutionary.

6.6.4. Ethics

This project deals with a near-future scenario; one where DDM and community workshops are near-ubiquity- for instance if one doesn't own a 3D printer, one knows somebody close who does. As such, any method of engaging people in this research means using novel methods of inclusion.

The Ethics procedure here at Sheffield Hallam University allowed for the development of this project, insofar as the use of patients was prohibited. The invitation to participate was offered on the basis that the participants joined in their capacity as *people* with lived experience of their chronic condition, rather than *patients*.

The ethical approval for this project at the University did not unduly hinder the work, although the project was not permitted to be 'open source' from its inception (5.3.2, p 89). In the future, it is hoped by the researcher that this work could inform the ethics committee of the importance of 'early opening' of projects, and the benefits this might bring.

There is a wider discussion to be had in the gathering of consent to participate in design projects. The researcher prepared forms to be filled out by participants and returned, ensuring that they had given their 'informed consent' to participate. However, after sending the forms out, and subsequently asking for their returned copies only one participant returned an informed consent sheet. The researcher informed all participants that they were free to participate in an anonymous or recognisable manner via the recruitment materials (static web page, Tumblr blog posts, welcome letter and landing page of the AIR site), all chose to be recognisable.

Does the designer bar access to a participant who is already collaborating in the design process? Is this behaviour not then a barrier to that person, who has decided that they want to contribute to the project?

Current ethics guidelines in the NHS do not take account for design projects. The ethics procedures in the NHS are primarily for the development and deployment of Randomised Control Trials (RCT)- the ethics process requires that the outcome of the research already be know to the best extent possible. However, in a generative design project, the exact nature of

the outcome is unknown. As discussed previously (2.4.1, p 19) this state of affairs exists because of the hierarchy of evidence in healthcare.

In order to tackle this impasse, design must be willing to consider the types of evidence required to evaluate and demonstrate efficacy of the methods used- but so too must the health sector be willing to treat other forms of evidence beyond rigidly quantitative methods (such as the RCT) as valid in developing artefacts to tame Wicked Problems in a health setting. After all, it should be recognised that while an RCT might be entirely appropriate for testing the efficacy of a new drug, it is perhaps inappropriate for testing the validity of a new health service; the richness of the circumstances surrounding it's success or failure being out of the RCT's scope to measure.

This requires that design (and designers) be willing to work in an open manner, one that is open to scrutiny (again the social expert). Once the shared aspects of the *practice* of both disciplines (design and healthcare) are seen to be similar (as describing them both as a *phronesis* – 2.7, p 28) it is the belief of the researcher that a significant barrier to the ethical approval of design projects within health will have been overcome.

6.7. Contribution to knowledge

This thesis, and the PhD it describes is based upon a novel implementation of Open Design to facilitate participation in the design process for those who are currently excluded. The PhD is intended to inform design practice by proposing a methodology for the Open Design of medical products that could be used by design practitioners.

Although the primary audience for this work are those designers, design managers and planners who work in the field of medical device design the methodological implications described here have far broader appeal. This open design methodology for the development of medical product prototypes is the contribution to knowledge.

6.8. Further work

Open Design can be a powerful tool to enable genuine collaboration in the design process by those who are currently excluded from the process. This PhD has highlighted the positive contribution that can be made by people who identify as creative people (Amber, Holly) and those who do not (Ronnie).

This PhD shows that mechanically complex products developed specifically for distributed manufacture are possible when facilitated by a professional designer, an online space (AIR), and means of production (MakerBot Replicator 3D printer, University workshop facilities mimicking a Fab Lab, etc.). These products are also meaningful, as they are borne out of the experience of those involved. The opportunity to make an impact on the redesign or development of an artefact that a person currently uses in their management of a chronic condition is a powerful motivating force for recruitment and engagement, as shown from the

enthusiastic work to design equipment for storage and expansion of Vest Therapy equipment in AIR (5.3.5, p 92).

Open Design is beginning to become more mainstream, and although there have been numerous 'open hardware' projects in the past (Raasch et al., 2009) these have not caught the public imagination like PhoneBloks (Hakkens, 2013) or Project ARA (Eremenko, 2013); both have posited concepts for open-source, modular hardware for smartphones. PhoneBloks and Motorola recently announced a partnership to develop designs for such a device, and the PhoneBloks community continues to grow. Google are poised to release their 'Hardware Development Kit' for people to build their own modules for the modular ARA phone, and as such the idea of a smartphone that can be customised at the point of sale, and also easily maintained has gained credibility in a wider context that did not previously exist. Questions about business models, intellectual property, manufacturing and ownership are all being tackled in the open.

This PhD is important, in that the researcher's work begins to tackle some of these key areas.

6.8.1. Recruitment and community nurture

Further research with industry partners, and producers of medical technology is required to answer the questions specific to recruitment for large Open Design projects. Smartphones have wide appeal, and as such recruitment for the Google ARA and PhoneBloks communities have been swift.

The sort of niche networks that might surround a medical product's development would perhaps not be as large, and finding the lead users, and nurturing their engagement will look different. The beginnings of this process are shown here in this thesis – further work to engage bigger communities, and influence policy makers is required.

6.8.2. Regulation and Standardisation

Similarly, the regulatory landscape for open hardware is not defined. Standardisation helps to enable safe operation and compliance of artefacts, yet the methods by which standards are made available and how these might be applied requires research. Some initial ideas for new funding / licensing models for the standards industry, and the mechanisms for applying these have been proposed (Dexter, Phillips, Atkinson & Baurley 2013). However, the process by which distributed manufacture of medical products is regulated has not yet begun in earnest. The conversations have been started (Ebenezer, 2013. pers. comm), and this work forms the basis of an initial example. Further work to highlight the regulatory impacts of more complex interventions and products is required.

6.9. Summary

The cat is out of the bag.

The democratisation of advanced methods of production, and the rapidly decreasing barrier to entry for professional design tools coupled with increasingly sophisticated networked communities will not cease. The design profession has evolved from professionals in siloed disciplines to incorporate the 'user' to an increasing degree, even to the status of partner and collaborator. Now, we must also be willing to relinquish control on a larger scale and allow for the amateur designers to produce for themselves. This process will require design's natural tendency towards social expertise (though social expertise is latent in some designers), and will mean further dissolution of the siloes that separate us in the design professions.

This research is timely, as it is a first step to understand the territory of Open Design practice and how this might have an impact on design in a health context- for instance by translating the work done by designers as a Phronesis, in the same terms as health practice. This is in contrast with attempting to 'make design fit' into methodological frameworks or theoretical perspectives currently dominating health practice (Evidence Based Practice is an example of this).

The work here leads on to future work around the processes, strategic design and certification of distributed manufacture- as well as the societal and economic impact that local design and production could make to communities and countries- communities of people who live with chronic conditions face varying treatment regimes in different locations, and Open Design offers an opportunity to understand, and disseminate best practice across global communities of people living with these chronic conditions.

The contribution to knowledge is an Open Design methodology for the production of medical product prototypes, and it is the intention of the researcher that this work informs design practice- profiling the benefits that Open Design can bring in addition to a traditional program of product development.

I am a *social expert.*

I have created this space for enabling collaborative design in an Open Design methodology. There are vast opportunities for Open Design across a myriad of sectors, and my experience and expertise in running using Open Design in health is an ideal point to begin the next phase of my career specialising in Open Design.

I believe this methodology has *much* to offer to the human race- perhaps even to bring about a future imagined by Schumacher, Illich and Gabor.

7. List of Figures

8. References

A

ACADEMYOFARTU (2011). *Academy of Art University | Web Design & New Media | A Conversation with Don Norman and Jon Kolko*. [online]. Presented by Richard Anderson. From YouTube last accessed 11th September 2013 at: http://www.youtube.com/watch?v=_SnagBGtJes&feature=youtu.be

ABELSON, J., FOREST, P.-G., EYLES, J., SMITH, P., MARTIN, E., & GAUVIN, F.-P. (2003). Deliberations about deliberative methods: issues in the design and evaluation of public participation processes. *Social Science & Medicine (1982)*, *57*(2), 239–51. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12765705

ACKOFF, R. L. (1997). Strategies, systems, and organizations: An interview with Russell L. Ackoff. *Strategy & Leadership*, *25*(2), 22–27. doi:10.1108/eb054582

ANDERSON, C. (2010). *Free: How today's smartest businesses profit by giving something for nothing* (p. 288). Random House Business. Retrieved from http://www.amazon.co.uk/Free-smartest-businesses-something-nothing/dp/190521149X

ANDERSON, Chris. (2012). *The New MakerBot Replicator Might Just Change Your World*. [online]. Last accessed 28th March 2014 at: http://www.wired.com/design/2012/09/how-makerbots-replicator2-will-launch-era-of-desktop-manufacturing/all/?pid=909#slideid-909

ARCHER, B. (1995). The Nature of Research. *CoDesign*, (January 1995), 6–13.

ARNSTEIN, S. (1969). A Ladder Of Citizen Participation. *Journal of the American Planning Association*, *35*(4), 216–224. doi:10.1080/01944366908977225

ATKINSON, P, MARSHALL, J, UNVER, E (2006). *Automake/FutureFactories*. Hub: the National Centre for Craft & Design, Sleaford, UK

ATKINSON, P. (2011). Orchestral Manoeuvers in Design. In B. Van Abel, L. Evers, L. Klaasen, & P. Troxler (Eds.), *Open Design Now*. Amsterdam: Bis B.V.

ATKINSON, P and ZHI, W (eds.) (2011). *Designing Impact! Approaches to Applied Research*. People's Republic of China, Foreign Languages Press, Beijing.

AVISON, D. E., Lau, F., Myers, M. D., & Nielsen, P. A. (1999). Action research. *Communications of the ACM*, *42*(1), 94–97. doi:10.1145/291469.291479

AVITAL, M. (2011). The Gererative Bedrock of Open Design. In B. Van Abel, L. Evers, L. Klaasen, & P. Troxler (Eds.), *Open Design Now*. Amsterdam: Bis B.V.

B

BAKER, S. A. (2012). From the criminal crowd to the "mediated crowd": the impact of social media on the 2011 English riots. *Safer Communities*, *11*(1), 40–49. doi:10.1108/17578041211200100

BANDOLIER. (2008). Evidence based thinking about healthcare. [online]. Last accessed 28th March 2014 at: http://www.medicine.ox.ac.uk/bandolier/index.html

BARDZELL, S. (2010). Feminist HCI. In *Proceedings of the 28th international conference on Human factors in computing systems - CHI '10* (p. 1301). New York, New York, USA: ACM Press. doi:10.1145/1753326.1753521

BARDZELL, S., & BARDZELL, J. (2011). Towards a feminist HCI methodology. In *Proceedings of the 2011 annual conference on Human factors in computing systems - CHI '11* (p. 675). New York, New York, USA: ACM Press. doi:10.1145/1978942.1979041

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

BATE, P., & ROBERT, G. (2006). Experience-based design: from redesigning the system around the patient to co-designing services with the patient. *Quality & Safety in Health Care*, *15*(5), 307–10. doi:10.1136/qshc.2005.016527

BATE, P., & ROBERT, G. (2007). *Bringing User Experience to Healthcare Improvement: The Concepts, Methods and Practices of Experience-based Design* (p. 224). Oxford, UK: Radcliffe Publishing Ltd. Retrieved from http://www.amazon.co.uk/Bringing-User-Experience-Healthcare-Improvement/dp/1846191769

BELLISSIMO, A., BURGESS, J., & FU, K. (2006). Secure software updates: disappointments and new challenges. *Proceedings of USENIX Hot Topics in ....* Retrieved from http://www.usenix.org/event/hotsec06/tech/full_papers/bellissimo/bellissimo.pdf

BERRY, D. M. (2004). The contestation of code. *Critical Discourse Studies*, *1*(1), 65–89. doi:10.1080/17405900410001674524

BEVAN, Kate (2007). Should Apple start manufacturing insulin pumps? [online]. The Guardian, 12th April. Last accessed 28th March 2014 at: http://www.guardian.co.uk/technology/2007/apr/12/guardianweeklytechnologysection.gadgets?INTCMP=SRCH

BJÖGVINSSON, E., EHN, P., & HILLGREN, P. (2012). Design Things and Design Thinking: Contemporary Participatory Design Challenges. *Design Issues*, *28*(3), 101–116. Retrieved from http://www.swetswise.com.lcproxy.shu.ac.uk/swoc-web/linkingDetails.html?openURL=false&issn=0747-9360&eissn=0747-9360&volume=28&issue=3&page=101

BJÖRGVINSSON, E. B. (2008). Open-ended participatory design as prototypical practice. *CoDesign*, *4*(2), 85–99. doi:10.1080/15710880802095400

BØDKER, M., NIELSEN, L., & ORNGREEN, R. N. (2007). Enabling user centered design processes in open source communities. In *Proceedings of the 2nd international conference on Usability and internationalization* (pp. 10–18). Springer-Verlag. doi:10.1007/978-3-540-73287-7_2

BOWEN, S. (2009). A critical artefact methodology: Using provocative conceptual designs to foster humancentred innovation. *Unpublished PhD Thesis. Sheffield Hallam University,*, (March). Retrieved from http://scholar.google.com/scholar?hl=en&btnG=Search&q=intitle:A+Critical+Artefact+Methodology+:#2

BOWEN, S., DEARDEN, A., & DEXTER, M. (2014). Wearing Two Hats: Reflecting Alongside Authentic Designing Authentic Design Practice. In *Design Research Society Conference* (pp. 1–13). Umeå, Sweden. Retrieved from http://www.drs2014.org/en/

BOWEN, S., DEARDEN, A., WOLSTENHOLME, D., COBB, M., & WRIGHT, P. (2011). Different Views: Including Others in Participatory Health Service Innovation. In J. Burr (Ed.), *Proceedings of PINC 2011* (pp. 230–236). Sønderborg, Denmark: University of Southern Denmark. Retrieved from http://shura.shu.ac.uk/3536/

BOWMAN, J. P., & RENSHAW, D. A. (1989). Desktop Publishing: Things Gutenberg Never Taught You. *Journal of Business Communication*, *26*(1), 57–77. doi:10.1177/002194368902600105

BOWYER, A (2011). Techique, Tradition & Technology. [presntation]. Held on the 9th December 2011 at the Victoria & Albert Museum, Sackler Centre for arts education

BOYD, D. M., & ELLISON, N. B. (2007). Social Network Sites: Definition, History, and Scholarship. *Journal of Computer-Mediated Communication*, *13*(1), 210–230. doi:10.1111/j.1083-6101.2007.00393.x

BRESLIN, M., & BUCHANAN, R. (2008). On the Case Study Method of Research and Teaching in Design. *Design Issues*, *24*(1), 36–40. doi:10.1162/desi.2008.24.1.36

BRIDGES, J., & NICHOLSON, C. (2008). Service improvement using patient narratives: engaging with the issues. *International Journal of Older People Nursing*, *3*(3), 217–22. doi:10.1111/j.1748-3743.2008.00130.x

BROWN, Rich. (2012). *Pulling back from open source hardware, MakerBot angers some adherents*. [online]. Last accessed 28th March 2014 at: http://news.cnet.com/8301-32973_3-57520633-296/pulling-back-from-open-source-hardware-makerbot-angers-some-adherents/

BROWN, T. (2009). *Change by Design: How Design Thinking Creates New Alternatives for Business and Society: How Design Thinking Can Transform Organizations and Inspire Innovation*. Collins Business. Retrieved from http://www.amazon.co.uk/Change-Design-Alternatives-Organizations-Innovation/dp/0061766089

BUCCIARELLI, L. L. (1996). *Designing Engineers (Inside Technology Series)* (p. 230). MIT Press. Retrieved from http://www.amazon.co.uk/Designing-Engineers-Inside-Technology-Series/dp/0262522128

BUCCIARELLI, L. L. (2002). Between thought and object in engineering design. *Design Studies*, *23*(3), 219–231. doi:10.1016/S0142-694X(01)00035-7

BUCHANAN, R. (1992). Wicked Problems in Design Thinking. *Design Issues*, *8*(2), 5–21. Retrieved from http://www.jstor.org/stable/1511637

BURKE, M. (1999). *Pirates of Silicon Valley*. USA: Turner Home Entertainment. Retrieved from http://alt.tntdrama.com//movies/tntoriginals/pirates/frame_index.htm

C

CARROLL, J., & ROSSON, M. (2007). Participatory design in community informatics. *Design Studies*, *28*(3), 243–261. doi:10.1016/j.destud.2007.02.007

CHAMBERLAIN, P. (2010). Horses, elephants and camels... : challenges and barriers to interdisciplinary user-centred design research. In D. MARJANOVIC, M. STORGA, N. PAVKOVIC, & N. BOJCETIC (Eds.), *Proceedings of DESIGN 2010, the 11th International Design Conference*. Dubrovnik, Croatia. Retrieved from http://shura.shu.ac.uk/4633/

CHAMBERLAIN, P., REED, H., BURTON, M., & MOUNTAIN, G. (2011). Future bathroom: A study of user-centred design principles affecting usability, safety and satisfaction in bathrooms for people living with disabilities. In *Research and development work relating to assistive technology 2010-11* (p. 136). UK Department of Health. Retrieved from https://www.gov.uk/government/publications/research-and-development-work-relating-to-assistive-technology-2010-11

CHAMBERLAIN, P., & YOXALL, A. (2012). "Of Mice and Men": The Role of Interactive Exhibitions as Research Tools for Inclusive Design. *The Design Journal*, *15*(1), 57–78. doi:10.2752/175630612X13192035508543

CHARNEY, D (2011). The Making Revolution – Professor Neil Gershenfeld in conversation with Daniel Charney. In: CHARNEY, D (ed) *The Power of Making: The Importance of being skilled*. London, V&A Publishing, 57-62

CHECKLAND, P., & HOLWELL, S. (1998). Action Research : Its Nature and Validity. *Systemic Practice and Action Research*, *11*(1), 9–21. doi:10.1023/A:1022908820784

CHESBROUGH, H. (2006). *Open Innovation : A New Paradigm for Understanding Industrial Innovation*. (H. Chesbrough, W. Vanhaverbeke, & J. West, Eds.) (p. 392). Oxford: Oxford University Press. Retrieved from http://www.amazon.com/Open-Innovation-Researching-New-Paradigm/dp/0199226466/ref=sr_1_1?ie=UTF8&qid=1368290585&sr=8-1&keywords=open+innovation+researching+a+new+paradigm

CHESBROUGH, H., & CROWTHER, A. K. (2006). Beyond high tech: early adopters of open innovation in other industries. *R and D Management*, *36*(3), 229–236. doi:10.1111/j.1467-9310.2006.00428.x

CHESBROUGH, H., & ROSENBLOOM, R. (2002). The role of the business model in capturing value from innovation: evidence from Xerox Corporation's technology spin-off companies. *Industrial and Corporate ...*, *11*(3), 529–555. doi:10.1093/icc/11.3.529

Chris Jackson @NorthwardsDS (2013). [online]. Tweet posted 19th January 2013 5:24am. Last accessed 28th March 2014 at: https://twitter.com/NorthwardsDS/status/292502745750069248

CLARK, S., & FU, K. (2012). Recent Results in Computer Security for Medical Devices. *Wireless Mobile Communication and Healthcare*, (October). Retrieved from http://link.springer.com/chapter/10.1007/978-3-642-29734-2_16

COTTAM, H., & LEADBEATER, C. (2004). *Health: Co-creating Services* (p. 57). London. Retrieved from http://www.designcouncil.info/RED/publications/publicationscontainer/RED_Paper 01 Health_Co-creating_services.pdf

CRAMPTON-SMITH, G., & TABOR, P. (1996). The Role of the Artist-Designer. In *Bringing Design to Software* (pp. 37–53). Palo Alto: ACM Press.

CROSS, N. (2007). *Designerly Ways of Knowing (Board of International Research in Design)* (p. 141). Basel | Boston | Berlin: Birkhäuser GmbH. Retrieved from http://www.amazon.co.uk/Designerly-Knowing-International-Research-Design/dp/3764384840

CROSS, N., & CLAYBURN CROSS, A. (1995). Observations of teamwork and social processes in design. *Design Studies*, *16*(2), 143–170. doi:10.1016/0142-694X(94)00007-Z

CROTTY, M. J. (1998). *The Foundations of Social Research: Meaning and Perspective in the Research Process* (p. 256). SAGE Publications Ltd. Retrieved from http://www.amazon.co.uk/The-Foundations-Social-Research-Perspective/dp/0761961062

CRUICKSHANK, L., & ATKINSON, P. (2013). Closing in on Open Design: comparing casual and critical design challenges. In *Crafting the Future: 10th European Academy of Design Conference* (pp. 1–15). Gothenburg. Retrieved from http://www.trippus.se/eventus/userfiles/39743.pdf

CUARTIELLES, David. (2012). *Arduino As Enabler of Open Design: Design using Open Source Hardware*. Presentation at the Open Design Symposium, Kunstuniversität Linz, Austria, May 23rd 2012. [online]. Last accessed 28th March 2014 at: http://www.open-design.at/videos/

CURTIS, A. (2011). All Watched Over By Machines Of Loving Grace. United Kingdom: BBC. Retrieved from http://www.bbc.co.uk/programmes/b011lvb9

D

DAHLANDER, L., & GANN, D. M. (2010). How open is innovation? *Research Policy*, *39*(6), 699–709. doi:10.1016/j.respol.2010.01.013

DAHLANDER, L., & WALLIN, M. W. (2006). A man on the inside: Unlocking communities as complementary assets. *Research Policy*, *35*(8), 1243–1259. doi:10.1016/j.respol.2006.09.011

DALKEY, N., & HELMER, O. (1963). An Experimental Application of the DELPHI Method to the Use of Experts. *Management Science*, *9*(3), 458–467. doi:10.1287/mnsc.9.3.458

DARLENSKI, R. B., NEYKOV, N. V., VLAHOV, V. D., & TSANKOV, N. K. (2010). Evidence-based medicine: facts and controversies. *Clinics in Dermatology*, *28*(5), 553–7. doi:10.1016/j.clindermatol.2010.03.015

DE MUL, J. (2011). Redesigning Design. In B. Van Abel, L. Evers, L. Klaasen, & P. Troxler (Eds.), *Open Design Now*. Amsterdam: Bis B.V.

DEWAR, B., MACKAY, R., SMITH, S., PULLIN, S., & TOCHER, R. (2009). Use of emotional touchpoints as a method of tapping into the experience of receiving compassionate care in a hospital setting. *Journal of Research in Nursing*, *15*(1), 29–41. doi:10.1177/1744987109352932

DEXTER, M., ATKINSON, P., & DEARDEN, A. M. (2013). Open Design and Medical Products: Irreconcilable Differences or Natural Bedfellows? In *Crafting the Future: 10th European Academy of Design Conference* (pp. 1–16). Gothenburg, Sweden.

DEXTER, M., & JACKSON, C. (2013). Making Space: the future places, tools and technologies for open Design. In P. Farias, L. Calvera, A. Braga, M. da Costa, & Z. Schincariol (Eds.), (pp. 348–352). São Paulo, Brazil: Blucher Design Proceedings. doi:10.5151/design-icdhs-067

DEXTER, Matt, PHILLIPS, Rob, ATKINSON, Paul, BAURLEY, Sharon. (2013). Standard Deviation: *Ensuring quality and replicability in Open Design practice.* Unpublished. Included in the Appendices for this thesis.

DORST, K. (2011). The core of "design thinking" and its application. *Design Studies*, *32*(6), 521–532. doi:10.1016/j.destud.2011.07.006

DRIVER, A., PERALTA, C., & MOULTRIE, J. (2011). Exploring how industrial designers can contribute to scientific research. *International Journal of Design*, *5*(1), 17–28. Retrieved from http://www.ijdesign.org/ojs/index.php/IJDesign/article/view/834

DRIVER, A., PERALTA, C., & MOULTRIE, J. (2012). *Design in Science: Exploring how industrial designers can contribute to scientific research* (1st ed., p. 130). Cambridge: The University of Cambridge.

E

EBENEZER, Neil. (2013). Head of New and Emerging Technology, United Kingdom Medicines and Medical Products Regulatory Agency. *Open Design & Standards*. Email to the author, 29th July 2013. Personal Communication.

EHN, P., & KYNG, M. (1991). Cardboard Computers: Mocking-it-up or Hands-on the Future. In *Design at Work: Cooperative Design of Computer Systems* (pp. 169–196). New York: CRC Press.

ENGLAND, I. (2012). *Reading The Riots* (p. 40). London. Retrieved from http://www.guardian.co.uk/uk/series/reading-the-riots

EREMENKO, Paul. (2013). Goodbye Sticky. Hello Ara. [online]. Last accessed 28th March 2014 at: http://motorola-blog.blogspot.co.uk/2013/10/goodbye-sticky-hello-ara.html

EVANS, B. (2010). Evidence Based Design. In *The World into Culture: Liber Amicorum Richard Focque (Comparative Methodologies)* (pp. 226–421). VUB University Press.

F

FARR, Nick. (2009). The Rights and Obligations of Hackerspace Members. [online]. Last accessed 28th March 2014 at: http://blog.hackerspaces.org/2009/08/19/rights-and-obligations-of-hackerspace-members/

FEDER, Barnaby J. (2008). *A Heart Device Is Found Vulnerable to Hacker Attacks*. [online]. Last accessed 28th March 2014 at: http://www.nytimes.com/2008/03/12/business/12heart-web.html?_r=2&

FISCHER, G., & SCHARFF, E. (2000). Meta-Design: Design for Designers. In *Proceedings of the conference on Designing interactive systems processes, practices, methods, and techniques - DIS '00* (pp. 396–405). New York, New York, USA: ACM Press. doi:10.1145/347642.347798

FLAHERTY, Joseph. (2012). *Cloning the MakerBot Is Legal, But Does That Make It Right?* [online]. Last accessed 28th March 2014 at: http://www.wired.com/design/2012/08/tangibot-makerbot-clone/

Food and Drug Administration. (2013. *FDA Safety Communication: Cybersecurity for Medical Devices and Hospital Networks*. [online]. Last accessed 28th March 2014 at: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm356423.htm

FRANCIS, L., & REYES, M. (2012). Social Media as a platform for Participatory Design. In K. Halskov, O. S. Iversen, M. Büscher, J. Simonsen, & K. Bødker (Eds.), *PDC 2012: Embracing New Territories of Participation* (pp. 89–92). Roskilde, Denmark: The Association for Computing Machinery.

FRANKE, N., & PILLER, F. (2004). Value Creation by Toolkits for User Innovation and Design: The Case of the Watch Market. *Journal of Product Innovation Management*, *21*(6), 401–415. doi:10.1111/j.0737-6782.2004.00094.x

FRAYLING, C. (1993). *Research in Art and Design. Royal College of Art Publications* (p. 7). London, UK: Royal College of Art. Retrieved from http://www.rca.ac.uk/Default.aspx?ContentID=510733

FUCHS, C. (2012). Social media, riots, and revolutions. *Capital & Class*, *36*(3), 383–391. doi:10.1177/0309816812453613

FÜLLER, J., BARTL, M., ERNST, H., & MÜHLBACHER, H. (2006). Community based innovation: How to integrate members of virtual communities into new product development. *Electronic Commerce Research*, *6*(1), 57–73. doi:10.1007/s10660-006-5988-7

G

GABOR, D. (1972). *The Proper Priorities Of Science And Technology* (1st ed., p. 17). Southampton: Camelot Press, Ltd.

GARRETY, K., & BADHAM, R. (2004). User-Centered Design and the Normative Politics of Technology. *Science, Technology, & Human Values*, *29*(2), 191–212. doi:10.1177/0162243903261946

GASSMANN, O. (2006). Opening up the innovation process: towards an agenda. *R and D Management*, *36*(3), 223–228. doi:10.1111/j.1467-9310.2006.00437.x

GAVER, B., & BOWERS, J. (2012). Annotated portfolios. *Interactions*, *19*(4), 40. doi:10.1145/2212877.2212889

GERSHENFELD, N. (2012). How to Make Almost Anything The Digital Fabrication Revolution. *Foreign Affairs*, *91*(6), 42–57. Retrieved from http://www.foreignaffairs.com/articles/138154/neil-gershenfeld/how-to-make-almost-anything

GISEBURT, Rob. (2012). *Is One of Our Open Source Heroes Going Closed Source?* [online]. Last accessed 28th March 2014 at: http://makezine.com/2012/09/19/is-one-of-our-open-source-heroes-going-closed-source/

GLANVILLE, R. (1999). Researching Design and Designing Research. *Design Issues*, *15*(2), 80–91. Retrieved from http://www.jstor.org.lcproxy.shu.ac.uk/stable/1511844

GOLDENBERG, M. J. (2006). On evidence and evidence-based medicine: lessons from the philosophy of science. *Social Science & Medicine (1982)*, *62*(11), 2621–32. doi:10.1016/j.socscimed.2005.11.031

GOLDSTEIN, J. (2007). The Role of Digital Networked Technologies in the Ukrainian Orange Revolution, *7641*. Retrieved from http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1077686##

GRENZFURTHNER, Johannes & SCHNEIDER, Frank (2009). // HACKING THE SPACES. [online]. Last accessed 28th March 2014 at: http://www.monochrom.at/hacking-the-spaces/

GRIFFITHS, A. L., JAMSEN, K., CARLIN, J. B., GRIMWOOD, K., CARZINO, R., Robinson, P. J., ... Armstrong, D. S. (2005). Effects of segregation on an epidemic Pseudomonas aeruginosa strain in a cystic fibrosis clinic. *American Journal of Respiratory and Critical Care Medicine*, *171*(9), 1020–5. doi:10.1164/rccm.200409-1194OC

H

HAKKENS, Dave. (2013). *Phonebloks*. [online]. Last accessed 1st April 2014 at: http://www.davehakkens.nl/work_phonebloks.html

HALPERIN, D., HEYDT-BENJAMIN, T. S., RANSFORD, B., CLARK, S. S., DEFEND, B., MORGAN, W., ... MAISEL, W. H. (2008). Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses. *2008 IEEE Symposium on Security and Privacy (sp 2008)*, 129–142. doi:10.1109/SP.2008.31

HANNA, S. (2011). Take two software updates and see me in the morning: The Case for Software Security Evaluations of Medical Devices. ... *on Health Security* ..., (August). Retrieved from http://www.contrib.andrew.cmu.edu/~ppoosank/papers/hanna-aed-healthsec11.pdf

HARFIELD, S. (2007). On design "problematization": Theorising differences in designed outcomes. *Design Studies*, *28*(2), 159–173. doi:10.1016/j.destud.2006.11.005

HAYES, G. R. (2011). The relationship of action research to human-computer interaction. *ACM Transactions on Computer-Human Interaction*, *18*(3), 1–20. doi:10.1145/1993060.1993065

HENNINGER, S., ELBAUM, S., & ROTHERMEL, G. (2005). Domain Specific User Centered Design for HCMDSS. In *High Confidence Medical Device Software and Systems (HCMDSS)* (pp. 1–4). Philadelphia. Retrieved from http://rtg.cis.upenn.edu/hcmdss/index.php3

HESS, J., & PIPEK, V. (2012). Community-Driven Development: Approaching Participatory Design in the Online World. *Design Issues*, *28*(3), 62–76. doi:10.1162/DESI_a_00162

HOLMES, D., MURRAY, S. J., PERRON, A., & RAIL, G. (2006). Deconstructing the evidence-based discourse in health sciences: truth, power and fascism. *International Journal of Evidence-Based Healthcare*, *4*(3), 180–6. doi:10.1111/j.1479-6988.2006.00041.x

HUNTER, K. (1996). "Don't think zebras": uncertainty, interpretation, and the place of paradox in clinical education. *Theoretical Medicine*, *17*(3), 225–41. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/8952419

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

HUTCHINS, E. (1996). *Cognition in the Wild (Bradford Books)* (p. 402). MIT Press. Retrieved from http://www.amazon.co.uk/Cognition-Bradford-Books-Edwin-Hutchins/dp/0262581469

I

IEDEMA, R., MERRICK, E., PIPER, D., BRITTON, K., GRAY, J., VERMA, R., & MANNING, N. (2010). Codesigning as a Discursive Practice in Emergency Health Services: The Architecture of Deliberation. *The Journal of Applied Behavioral Science*, *46*(1), 73–91. doi:10.1177/0021886309357544

ILLICH, I. (2001). *Tools for Conviviality* (p. 128). Marion Boyars. Retrieved from http://www.amazon.co.uk/Tools-Conviviality-Ivan-Illich/dp/1842300113

J

JHOWARD (2013). *The 100,000th Thing on Thingiverse!* [online]. Last accessed 28th March 2014 at: http://www.makerbot.com/blog/2013/06/08/100000th-thing-on-thingiverse/

JONES, R., HAUFE, P., SELLS, E., IRAVANI, P., OLLIVER, V., PALMER, C., & BOWYER, A. (2011). RepRap – the replicating rapid prototyper. *Robotica*, *29*(01), 177–191. doi:10.1017/S026357471000069X

K

KADUSHEN, R (2010). Open Design Manifesto. [online]. Last accessed 29th April 2012 at: http://www.ronen-kadushin.com/uploads/2440/Open%20Design%20Manifesto-Ronen%20Kadushin%20.pdf

KADUSHEN, R (2012). Open Design – *Products in a networked culture*. Presentation at The Open Design Symposium Linz, Audimax of the Kunstuniversität Linz, Austria, May 23rd 2012.

KALIL, T. (2009). Harnessing the Mobile Revolution. *Innovations: Technology, Governance, Globalization*, *4*(1), 9–23. doi:10.1162/itgg.2009.4.1.9

KARLSSON, I. C. M., ENGELBREKTSSON, P., LARSSON, L. E., PARETO, L., SNIS, U. L., BERNDTSSON, B., & SVENSSON, L. (2011). Use-centred design of medical

and healthcare technology: a pilot study of field tests as a development tool. *International Journal of Biomedical Engineering and Technology*, *5*(1), 11. doi:10.1504/IJBET.2011.038470

KATZ, A. (2011). Authors And Owners. In B. Van Abel, L. Evers, L. Klaasen, & P. Troxler (Eds.), *Open Design Now*. Amsterdam: Bis B.V.

KEEN, A. (2007). *The Cult of the Amateur: How Today's Internet Is Killing Our Culture and Assaulting Our Economy* (p. 240). London: Nicholas Brealey Publishing. Retrieved from http://www.amazon.co.uk/Cult-Amateur-Internet-Killing-Assaulting/dp/1857883934

KELLY, J., & MATTHEWS, B. (2010). Taking transition into account. In *Proceedings of the 11th Biennial Participatory Design Conference on - PDC '10* (p. 71). New York, New York, USA: ACM Press. doi:10.1145/1900441.1900452

KENSING, F., & BLOMBERG, J. (1998). Participatory design: Issues and concerns. *Computer Supported Cooperative Work (CSCW)*, (1993), 167–185. doi:10.1023/A:1008689307411

KESTER, David (2011). *Nudge by Design*. Presentation at the Intersections 11 Business Design Summit, Eden Project, 2nd March 2011.

KING, J. B. (1993). Learning to solve the right problems: The case of nuclear power in America. *Journal of Business Ethics*, *12*(2), 105–116. doi:10.1007/BF00871930

KRIPPENDORFF, K. (2007). Design research, an oxymoron? *Design Research Now*. doi:10.1007/978-3-7643-8472-2_5

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/

KUMAR, S., HEDRICK, M., WIACEK, C., & MESSNER, J. (2011). Developing an experienced-based design review application for healthcare facilities using a 3d game engine. *Use of Gaming Technology in Architecture, Engineering and Construction*, *16*(June 2010), 85–104. Retrieved from http://itcon.org/cgi-bin/works/Show?_id=2011_6

KUNZ, W., & RITTEL, H. W. J. (1972). Information science: On the structure of its problems. *Information Storage and Retrieval*, *8*(2), 95–98. doi:10.1016/0020-0271(72)90011-3

KVAN, T. (2000). Collaborative design: what is it? *Automation in Construction*, *9*(4), 409–415. doi:10.1016/S0926-5805(99)00025-4

L

LAURSEN, K., & SALTER, A. (2006). Open for innovation: the role of openness in explaining innovation performance among U.K. manufacturing firms. *Strategic Management Journal*, *27*(2), 131–150. doi:10.1002/smj.507

LEADBEATER, C. (2009). *We-Think: Mass innovation, not mass production* (p. 336). Profile Books. Retrieved from http://www.amazon.co.uk/We-Think-Mass-innovation-mass-production/dp/1861978375

LEHOUX, P., HIVON, M., WILLIAMS-JONES, B., & URBACH, D. (2011). The worlds and modalities of engagement of design participants: A qualitative case study of three medical innovations. *Design Studies*, *32*(4), 313–332. doi:10.1016/j.destud.2011.01.001

LLOYD, G., & SASSON, S. (1978). Electronic still camera. *US Patent 4,131,919*. USA: USPTO. Retrieved from http://www.google.com/patents?hl=en&lr=&vid=USPAT4131919&id=eYQ0AAAAEBAJ&oi=fnd&dq=Electronic+still+camera&printsec=abstract

LOMEE, Thomas. (2014). *OpenStructures*. [online]. Last accessed 28th March 2014 at: http://www.openstructures.net/.

LUCK, R. (2007). Learning to talk to users in participatory design situations. *Design Studies*, *28*(3), 217–242. doi:10.1016/j.destud.2007.02.002

M

MAGEE, B. (1974). *Popper* (p. 109). London, UK: The Woburn Press.

MAHESH, M., ONG, S. K., & NEE, a. Y. C. (2007). A web-based multi-agent system for distributed digital manufacturing. *International Journal of Computer Integrated Manufacturing*, *20*(1), 11–27. doi:10.1080/09511920600710927

MAHESH, M., ONG, S. K., NEE, a. Y. C., FUH, J. Y. H., & ZHANG, Y. F. (2007). Towards a generic distributed and collaborative digital manufacturing. *Robotics and Computer-Integrated Manufacturing*, *23*(3), 267–275. doi:10.1016/j.rcim.2006.02.008

MARCUM, J. a. (2008). Montgomery, Kathryn, How Doctors Think: Clinical Judgment and the Practice of Medicine. *Theoretical Medicine and Bioethics*, *28*(6), 525–530. doi:10.1007/s11017-007-9056-7

MARI, E. (2002). *Autoprogettazione? Ediz. italiana e inglese*. Corraini. Retrieved from http://www.amazon.co.uk/Autoprogettazione-Ediz-italiana-inglese-Enzo/dp/8887942676

MARKS, D. F. (2002). *Perspectives on evidence-based practice* (pp. 1–53). Retrieved from http://www.nice.org.uk/aboutnice/whoweare/aboutthehda/evidencebase/publicheal thevidencesteeringgroupproceedings/perspectives_on_evidence_based_practice.jsp

MARTIN, J. L., & BARNETT, J. (2012). Integrating the results of user research into medical device development: insights from a case study. *BMC Medical Informatics and Decision Making*, *12*, 74. doi:10.1186/1472-6947-12-74

McCARTHY, Richard. (2012). *Our Lawyer Explains The Thingiverse Terms Of Service*. [online]. Last accessed 28th March 2014 at: http://www.makerbot.com/blog/2012/09/26/our-lawyer-explains-the-thingiverse-terms-of-service/#sthash.tb4ADsZL.dpuf

McFAUL, M. (2005). Transitions from Postcommunism. *Journal of Democracy*, *16*(3), 5–19. doi:10.1353/jod.2005.0049

MEADOWS, D. H., MEADOWS, D., RANDERS, J., & BEHRENS III, W. W. (1972). *The Limits to Growth* (p. 211). New York: Universe Books.

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

MENCHENELLI, M (2012). *Meet My Maker*. [online]. Last accessed 29th April 2012 at: http://www.openp2pdesign.org/2012/fabbing/an-interview-with-bas-van-abel-about-open-design/#more-2088

MIER, Joe. (2013). *Design Bootcamp: Results*. [online]. Last accessed 1st April 2014 at: http://www.fairphone.com/2013/06/12/design-bootcamp-results/

MOILANEN, J., & VADÉN, T. (2013). 3D printing community and emerging practices of peer production. *First Monday*, *18*(8), 1–17. doi:10.5210%2Ffm.v18i8.4271

MONEY, A. G., BARNETT, J., KULJIS, J., CRAVEN, M. P., MARTIN, J. L., & YOUNG, T. (2011). The role of the user within the medical device design and development process: medical device manufacturers' perspectives. *BMC Medical Informatics and Decision Making*, *11*(1), 15. doi:10.1186/1472-6947-11-15

MONTGOMERY, K. (2005). *How Doctors Think: Clinical judgment and the practice of medicine: Clinical Judgement and the Practice of Medicine* (p. 208). OUP USA. Retrieved from http://www.amazon.co.uk/How-Doctors-Think-Clinical-Judgement/dp/0195187121

MOROZOV, E. (2012). *The Net Delusion: How Not to Liberate The World* (p. 432). St. Ives: Penguin. Retrieved from http://www.amazon.co.uk/Net-Delusion-How-Liberate-World/dp/014104957X/ref=sr_1_2?s=books&ie=UTF8&qid=1396024124&sr=1-2&keywords=morozov

MOWERY, D. C. (1983). The relationship between intrafirm and contractual forms of industrial research in American manufacturing, 1900–1940. *Explorations in Economic History*, *20*(4), 351–374. doi:10.1016/0014-4983(83)90024-4

MÜLLERT, N., & JUNGK, R. (1987). *Future workshops How to create desirable futures* (2Rev Ed ed., p. 126). London: Institute for Social Inventions.

N

NAMBISAN, S., & SAWHNEY, M. (2010). Making the Most of the Global Brain for Innovation. *International Commerce Review*, *8*(2-4), 128–135. doi:10.1007/s12146-010-0042-z

NELSON, G. M., SALMON, M. A. P., ALTMAN, H. K., & SPRIGG, P. E. (2012). Organizing communities around care transitions: the community connections experience. *North Carolina Medical Journal*, *73*(1), 41–4. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/22619853

NOBLE, A., & ROBINSON, C. (2000). For The Love of the People: Participatory Design in a Community Context. In S. A. R. Scrivener (Ed.), *Collaborative Design* (p. 81). London: Springer-Verlag.

NUVOLARI, A. (2004). Collective invention during the British Industrial Revolution: the case of the Cornish pumping engine. *Cambridge Journal of Economics*, *28*(3), 347–363. doi:10.1093/cje/bch011

O

OPEN KNOWLEDGE FOUNDATION (2012). *Our Current Projects*. [online]. Last accessed 26th April 2012 at: http://design.okfn.org/current-projects/

OWENS, C., FARRAND, P., DARVILL, R., EMMENS, T., HEWIS, E., & AITKEN, P. (2011). Involving service users in intervention design: a participatory approach to developing a text-messaging intervention to reduce repetition of self-harm. *Health Expectations : An International Journal of Public Participation in Health Care and Health Policy*, *14*(3), 285–95. doi:10.1111/j.1369-7625.2010.00623.x

P

PALLASMAA, J. (2009). *The Thinking Hand (Architectural Design Primer)* (p. 160). John Wiley & Sons. Retrieved from http://www.amazon.co.uk/Thinking-Hand-Architectural-Design-Primer/dp/0470779292

PARK, J. Y. (2012). Design process excludes users: the co-creation activities between user and designer. *Digital Creativity*, *23*(1), 79–92. doi:10.1080/14626268.2012.658814

PEARSON, H. E. (2000). OPEN SOURCE LICENCES. *Computer Law & Security Review*, *16*(3), 151–156. doi:10.1016/S0267-3649(00)88906-2

PELLING, N (2011). *Aiming (much) higher than Hackspaces and FabLabs...* [online]. Last accessed 28th March 2014 at: http://nanodome.wordpress.com/2011/11/13/aiming-much-higher-than-hackspaces-and-fablabs/

PETTIS, B & ASTERA, (2008). *Hackerspaces: the_beginning*. [online]. Last accessed 20th December 2011 at: http://blog.hackerspaces.org/2011/08/31/hackerspaces-the-beginning-the-book/

PETTIS, B (2011). Techique, Tradition & Technology. [presntation]. Held on the 9th December 2011 at the Victoria & Albert Museum, Sackler Centre for arts education

PETTIS, B (2012). *Fixing Misinformation with Information*. [online]. Last accessed 28th March 2014 at: http://www.makerbot.com/blog/2012/09/20/fixing-misinformation-with-information/

PETTIS, B (2012). *Let's try that again*. [online]. Last accessed 28th March 2014 at: http://www.makerbot.com/blog/2012/09/24/lets-try-that-again/

PICKLES, J., HIDE, E., & MAHER, L. (2008). Experience based design: a practical method of working with patients to redesign services. *Clinical Governance: An International Journal*, *13*(1), 51–58. doi:10.1108/14777270810850634

PIPEK, V., & WULF, V. (2009). Infrastructuring : Toward an Integrated Perspective on the Design and Use of Information Technology. *Journal of the Association for Information Systems*, *10*(May 2009), 447–473. Retrieved from http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.163.9558&rep=rep1&type=pdf

POLANYI, M. (1966). *The Tacit Dimension* (1st ed., p. 25). New York: Doubleday New York. Retrieved from http://www.chaight.com/Wk 8 E205B Polanyi - Tacit Knowing.pdf

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

PRESTON-WERNER, Tom (2011). *Open Source (Almost) Everything*. [online]. Last accessed 28th March 2014 at: http://tom.preston-werner.com/2011/11/22/open-source-everything.html

PRŮŠA, Josef. (2012). *Open Hardware meaning*. [online]. Last accessed 28th March 2014 at: http://josefprusa.cz/open-hardware-meaning/

R

RAASCH, C., HERSTATT, C., & BALKA, K. (2009). On the open design of tangible goods. *R&D Management, 39*(4), 382–393. doi:10.1111/j.1467-9310.2009.00567.x

RAISIO, H. (2009). Health care reform planners and wicked problems: Is the wickedness of the problems taken seriously or is it even noticed at all? *Journal of Health Organisation and Management, 23*(5), 477–493. doi:10.1108/14777260910983989

RAND, P. (1993). *Design Form and Chaos* (1st ed., p. 218). New Haven and London: Yale University Press.

RAYMOND, E. (1999). The cathedral and the bazaar. *Knowledge, Technology & Policy, 12*(3), 23–49. doi:10.1007/s12130-999-1026-0

RAYMOND, E. (2001a). A Brief History of Hackerdom. In *The Cathedral and the Bazaar* (pp. 1–19). Cambridge, Massachusetts: O'Reilly. Retrieved from http://www.immagic.com/eLibrary/ARCHIVES/GENERAL/AUTHOR_P/R000825P.pdf

RAYMOND, E. (2001b). Homesteading The Noosphere. In *The Cathedral and the Bazaar* (pp. 65–113). Cambridge, Massachusetts: O'Reilly. Retrieved from http://firstmonday.org/ojs/index.php/fm/article/viewArticle/621

RAYMOND, E. (2001c). The Magic Cauldron. In *The Cathedral and the Bazaar* (pp. 113–167). Cambridge, Massachusetts: O'Reilly. Retrieved from http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.196.9716&rep=rep1&type=pdf

REASON, P., & BRADBURY, H. (2005). *Handbook of Action Research: Concise Paperback Edition: Student Edition* (p. 400). Sage Publications Ltd. Retrieved from http://www.amazon.co.uk/Handbook-Action-Research-Concise-Paperback/dp/1412920302

RIVLIN, Gary. (2011). Chain of DIY Stores Sparks Inventions. [online]. Last accessed 28th March 2014 at: http://www.newsweek.com/chain-diy-stores-sparks-inventions-68019

ROSENHEAD, J. (1978). Operational research in health services planning. *European Journal of Operational Research, 2*(2), 75–85. doi:10.1016/0377-2217(78)90103-0

RUST, C. (2007). Unstated contributions: how artistic inquiry can inform interdisciplinary research. *International Journal of Design*, *1*(3), 69–76. Retrieved from http://shura.shu.ac.uk/966/

RYCROFT-MALONE, J., SEERS, K., TITCHEN, A., HARVEY, G., KITSON, A., & McCORMACK, B. (2004). What counts as evidence in evidence-based practice? *Journal of Advanced Nursing*, *47*(1), 81–90. doi:10.1111/j.1365-2648.2004.03068.x

S

SABATE, E. (2003). *Adherence to Long Term Therapies: Evidence for Action*. (E. Sabaté, Ed.) (p. 196). Geneva: World Health Organization. Retrieved from http://www.who.int/iris/handle/10665/42682#sthash.GD9f8P6X.dpuf

SACKETT, D. L., ROSENBERG, W. M. C., GRAY, J. A. M., HAYNES, R. B., & RICHARDSON, W. S. (1996). Evidence based medicine: what it is and what it isn't. *BMJ*, *312*(7023), 71–72. doi:10.1136/bmj.312.7023.71

SANDERS, E. B.-N., & STAPPERS, P. J. (2008). Co-creation and the new landscapes of design. *CoDesign*, *4*(1), 5–18. doi:10.1080/15710880701875068

SEIDLE, N (2012). *IP Obesity*. [online]. Last accessed 28th March 2014 at: https://www.sparkfun.com/news/963

SCHUMACHER, E. F. (2011). *Small Is Beautiful: A Study of Economics as if People Mattered* (p. 288). Vintage. Retrieved from http://www.amazon.co.uk/Small-Beautiful-Economics-People-Mattered/dp/0099225611

SENNETT, R. (2009). *The Craftsman* (p. 336). Penguin. Retrieved from http://www.amazon.co.uk/The-Craftsman-Richard-Sennett/dp/0141022094

SHAH, S. G. S., & ROBINSON, I. (2006). User involvement in healthcare technology development and assessment: Structured literature review. *International Journal of Health Care Quality Assurance*, *19*(6), 500–515. doi:10.1108/09526860610687619

SHAH, S. G. S., & ROBINSON, I. (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), 131–7. doi:10.1017/S0266462307051677

SHAH, S. G. S., & ROBINSON, I. (2008). Medical device technologies: who is the user? *International Journal of Healthcare Technology and Management*, *9*(2), 181. doi:10.1504/IJHTM.2008.017372

SHAH, S. G. S., ROBINSON, I., & ALSHAWI, S. (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), 514–21. doi:10.1017/S0266462309990328

SHAPEWAYS (2012). Teenage Engineering Make CAD Files Available to 3D Print Replacement Parts. [online]. Last accessed 28th March 2014 at: http://www.shapeways.com/blog/archives/1647-teenage-engineering-make-cad-files-available-to-3d-print-replacement-parts.html

SHOWELL, C. M. (2011). Citizens, Patients and Policy: A Challenge for Australia's National Electronic Health Record. *Health Information Management Journal, 40*(2), 39–43.

SIMONSEN, J., & ROBERTSON, T. (2012). *Routledge International Handbook of Participatory Design (Routledge International Handbooks)* (p. 320). Routledge. Retrieved from http://www.amazon.co.uk/Routledge-International-Handbook-Participatory-Handbooks/dp/041569440X

SINCLAIR, Matt. (2012). *Bemused by the Hype Surrounding Cubify? Me Too*. [online]. Last accessed 28th March 2014 at: http://no-retro.com/home/

SMITH, Kevin. (2012). *Now Anyone Can Use 3D Printing To Make Money*. [online]. Last accessed 28th March 2014 at: http://www.businessinsider.com/shapeways-3d-printing-2012-12#ixzz2xGj9FukK

SMITH, Zachary. (2012). *MakerBot vs. Open Source – A Founder Perspective*. [online]. Last accessed 28th March 2014 at: http://www.hoektronics.com/2012/09/21/makerbot-and-open-source-a-founder-perspective/

SPINUZZI, C. (2005). The Methodology of Participatory Design. *Technical Communication, 52*(2), 163–174. Retrieved from http://search.proquest.com.lcproxy.shu.ac.uk/docview/220962011/abstract?accountid=13827

STEEN, M. (2012). Virtues in Participatory Design: Cooperation, Curiosity, Creativity, Empowerment and Reflexivity. *Science and Engineering Ethics*, (2008). doi:10.1007/s11948-012-9380-9

STETLER, C. B., BRUNELL, M., GIULIANO, K. K., MORSI, D., PRINCE, L., & NEWELL-STOKES, V. (1998). Evidence-based practice and the role of nursing leadership. *The Journal of Nursing Administration, 28*(7-8), 45–53. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/21401858

STICKDORN, M., & SCHNEIDER, J. (2012). *This is Service Design Thinking* (p. 376). Amsterdam: Bis B.V. Retrieved from http://www.amazon.co.uk/This-service-design-thinking-druk/dp/906369279X/ref=sr_1_1?s=books&ie=UTF8&qid=1396010377&sr=1-1&keywords=this+is+service+design+thinking

STILGHERRIAN. (2012). *Cyborg lawyer demands software source*. [online]. Last accessed 28th March 2014 at: http://www.zdnet.com/cyborg-lawyer-demands-software-source-1339330089/

SUROWIECKI, J. (2005). *The Wisdom of Crowds: Why the Many Are Smarter Than the Few* (p. 295). Abacus. Retrieved from http://www.amazon.co.uk/The-Wisdom-Crowds-Many-Smarter/dp/0349116059

SZCZYS, Mike. (2013). Cube 3D printer hack lets you use bulk filament. [online]. Last accessed 28th March 2014 at: http://hackaday.com/2013/04/26/cube-3d-printer-hack-lets-you-use-bulk-filament/

T

TILDEN, S. (1987). Harnessing desktop publishing: How to let the new technology help you do your job better. Pennington, NJ: Scott Tilden.

TIGOE. (2012). *In defense of open source innovation and polite disagreement.* [online]. Last accessed 28th March 2014 at: http://www.tigoe.net/blog/category/open-innovation/408/

TONKIN, E., PFEIFFER, H. D., & TOURTE, G. (2012). Twitter, information sharing and the London riots? *Bulletin of the American Society for Information Science and Technology*, *38*(2), 49–57. doi:10.1002/bult.2012.1720380212

TORRONE, Phillip. (2012). *Soapbox: The {Unspoken} Rules of Open Source Hardware.* [online]. Last accessed 28th March 2014 at: http://makezine.com/2012/02/14/soapbox-the-unspoken-rules-of-open-source-hardware/

TROXLER, P. (2011). Libraries Of The Peer Production Era. In B. Van Abel, L. Evers, L. Klaasen, & P. Troxler (Eds.), *Open Design Now.* Amsterdam: Bis B.V.

TSIANAKAS, V., MABEN, J., WISEMAN, T., ROBERT, G., RICHARDSON, A., MADDEN, P., … DAVIES, E. a. (2012). Using patients' experiences to identify priorities for quality improvement in breast cancer care: patient narratives, surveys or both? *BMC Health Services Research*, *12*(1), 271. doi:10.1186/1472-6963-12-271

U

UBBINK, D. T., GUYATT, G. H., & VERMEULEN, H. (2013). Framework of policy recommendations for implementation of evidence-based practice: a systematic scoping review. *BMJ Open*, *3*(1). doi:10.1136/bmjopen-2012-001881

UKIPO (2008). *Moral rights.* [online]. Last accessed 28th March 2014 at: http://www.ipo.gov.uk/types/copy/c-otherprotect/c-moralrights.htm

V

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

VON BUSCH, O. (2012). Generation Open: Contested Creativity and Capabilities. *The Design Journal*, *15*(4), 443–459. doi:10.2752/175630612X13437472804295

Von HIPPEL, E. (1986). Lead Users: A Source of Novel Product Concepts. *Management Science*, *32*(7), 791–805. doi:10.1287/mnsc.32.7.791

Von HIPPEL, E. (2005). *Democratizing Innovation. Journal of Product Innovation Management* (Vol. 23, p. 204). Cambridge, Massachusetts: MIT Press. Retrieved from http://doi.wiley.com/10.1111/j.1540-5885.2006.00192_2.x

W

WANLESS, D. (2002). *Securing our Future Health: Taking a Long-Term View* (p. 179). London. Retrieved from http://www.yearofcare.co.uk/sites/default/files/images/Wanless.pdf

WEIGEL, S. (2011). Medical Technology's Source of Innovation. *European Planning Studies*, *19*(1), 43–61. doi:10.1080/09654313.2011.530391

WEST, J. (2003). How open is open enough? *Research Policy*, *32*(7), 1259–1285. doi:10.1016/S0048-7333(03)00052-0

WHO (1948). Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

WHYTE, W. F. (1989). Advancing scientific knowledge through participatory action research. *Sociological Forum*, *4*(3), 367–385. doi:10.1007/BF01115015

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

WINNER, L. (1993). Upon Opening the Black Box and Finding It Empty: Social Constructivism and the Philosophy of Technology. *Science, Technology & Human Values*, *18*(3), 362–378. doi:10.1177/016224399301800306

WOLSTENHOLME, D., COBB, M., BOWEN, S., WRIGHT, P., & DEARDEN, A. (2010). Design-Led Service Improvement for Older People. *Australasian Medical Journal*, 465–470. doi:10.4066/AMJ.2010.377

9. Appendices

9.1. Appendix A - *Reflective Log*

This document is the summary of the activity conducted during the main PhD case study.

90 pages.

Reflective Log | Table of Contents

Introduction

This document is the reflective log for the research activity contained in the main PhD case study. It is informally written, being my own reflections on the design activity taking place in AIR. This document should be used alongside the web space, thesis and prototypes to build a picture of the Open Design activity, and why this can be considered a piece of research.

Guiding the research activity is Action Research, and in order for this generative research to be *considered* research, the assumptions and preconceptions of the researcher need to be recorded- before the action cycles, and also during the activity.

Phase Zero

This document is a first attempt to document my own reflections working on the first 'phase zero' of the diabetes project- designing the tools for engaging the 'disengaged'.

Rationale for 'Phase Zero'

The theory being used was that there is a distinct group of people, who are not 'engaging' with their diabetes. We as the design team were aware that people with diabetes are not a homogeneous group, and that 'engagement' was more of a continuum rather than two fixed binary values. For instance, the graph that Simon and Dan produced plotting an imaginary line of 'compliance' against time, was given 'the nod' by specialist diabetes clinicians. As such, the basis of phase one was the idea that while we had no experience of what it was like to be an adolescent with T1D in 2011/2012, we might be able to recruit someone who was 'engaged' with their diabetes to co-design these tools- since they would have a unique insight into both lived experience of T1D and that as a modern adolescent.

While we perhaps had a good grasp of this aspect the fact that adolescents who have T1D are not a homogeneous group, perhaps did not pervade the day-to-day thinking behind the rationale for phase zero. For instance, there were certain well-meaning but flawed assumptions that were carried through the design process, linked mostly to current youth culture.

The idea that phase zero represented an exercise in designing the tools to approach the 'disengaged' proved to be a subtle point. So subtle, in fact, that we as the design team had to make a constant effort to not fall into the trap of moving straight to phase one. This problem was exacerbated when we worked with other people; we struggled in the RYDA / Barnsley meetings to articulate this point, and as such we found people moving straight to phase one.

Initial design work

I started work on phase zero in mid-January 2011. At this point, there was a feeling that we should look to produce an online meeting space that would serve as a way to bring people together and to design these 'tools for the disengaged'. This was borne of Füller et al (2006)'s paper on *community-based innovation*. The idea that we might create a node at which people might come and share their creative input seemed very enticing- after all; there are a number of successful instances of creative crowdsourcing.

Hindsight is of course, 20:20. We certainly fell into the trap of 'if you build it, they will come', even if we verbally acknowledged that this was nonsense. Immediately Dan and I began work on a wish list of what such a space should be, and contain. These were not

planned meetings per-se, but constant conversations that we had over the first week of work. The first, very rough, draft of what the space looked like was produced within that first week. Because these conversations took place in the office, and they were not necessarily fixed meetings, this lead to the communication issues that became apparent between the design activity and the implementation activity. It is obvious to see when this is written down that these *should not* have been separate entities- and that the discussions about what the space should include should have included everyone... hence discussing the work in the office. The creation of lists and action points, while useful in prototyping an idea, is a poor way to conduct an ideation exercise.

This miscommunication stunted the growth of the design, and the prototyping effort. The adage 'fail early, fail often' sadly could not work in this instance, because prototyping the space took such a long time. It was difficult to assess what ideas were feasible, and how long or how much these ideas might take/cost. There were also lots of discussions about what platform to use, and whether more resource was needed for the programming effort, in order to implement the ideas that had been suggested. It is worth noting that the ideas for the space, and how it should look all had a rationale, and it seems these prototyping issues all stem from internal communication problems.

Incentives

As the prototype was being developed, we recognized that there was a potential problem with people not wanting to participate. This problem was also compounded by the requirements to give everyone who wanted to participate in the space informed consent. The consent information was long, and whilst this was rewritten to a more condensed and readable form it was still felt that this was too much of a barrier to people participating. As such, Dan and I embarked on a process of creating video content that explained the outline of the project and the consent information in a short, very visual way. We were able to get the video down to 1 minute, whilst still covering all of the main points in the consent document.

There was still the issue of *informed* consent- we had to have the people entering the site make a choice about their willingness to participate. As such, the consent process was actually a series of 3 web pages, where people were introduced to the project, could read the information, and then make a choice about whether to participate, and whether they wanted to be recognisable or anonymous. As we were developing this process, we were aware that this barrier to entry might be still too high. We were anxious to not 'bury' the information, as this was considered an 'unethical' procedure in this case. Companies such as Facebook and Apple bury EULA information in incomprehensible legal jargon, and give the person the choice to skip all this important info.

We wanted to pre-empt the question of whether we should use incentives at a later date by discussing it with Peter Wright. The level of incentive used was a hot topic, and in the end we decided that we needed to reward contributions by allowing the space to alter – that is, give low-level feedback and 'badges' to the participants rewarding their contributions. A little like the system used by openIDEO. In the end, we offered a £20 Amazon voucher for participants, but as we found with other websites offering an iPod Touch or Nintendo 3DS for contributing ideas, our implementation of an incentive was not as persuasive.

Testing

Since the prototype took so long, once content had been created and implemented in the space and demonstrated, the sharp feedback we were given by Getting Sorted left very little room for manoeuvre, since the deadline for rolling out the web space had already been pushed back a few times.

There were real concerns about the presentation of the informed consent, and the delivery of this via the introductory video and written content. There were also more low-level concerns about the look-and-feel of the website. As such, we hired the help of Tony and Sara to re shoot the introductory video, and rewrite the videos that formed the help section to allow people to navigate. It was interesting to note that Tony and Sara were not in the target group that we wanted to talk to, but it was felt that a more authoritative voice would help to bring people on board, and get them interested in the project. It was also apparent that the style of the communication (while desperately trying to avoid a paternal, 'authoritative' tone) was wide of the mark, which was a substantive part of the criticism from Getting Sorted.

The site itself was picked up on for the way it was used. Several times the mention of 'Facebook' came up, which seems to chime with the way Tom Hulme discusses the development of openIDEO – meeting people where they are (in a social network) and with tools they understand (FB sharing of videos, etc and the paradigm of 'posting' your content).

Recruitment

Continuing the theme of building an online community (Füller et al, 2006), we looked for people to participate who already discussed their experiences of living with T1D online, in the form of blogs. These bloggers shared their experiences, and in some cases their blogs were rich pictures of a teenager's whole experience- giving lots of contextual information about adolescent culture as it stands today.

However, looking back it seems an important step was missed; Füller et al, and openIDEO both went to where people were, and recruited from there. In Füller et al, they invited visitors to Audi's website into the design space- the people visiting Audi's

website had an interest in the brand, and therefore were very likely to accept the invitation and participate. OpenIDEO similarly originally started their community on Facebook, and when it had grown to a large enough size it was spun out as a distinct company with a community. The people were already *there*.

The problem with contacting bloggers (whether they had a distinct blog, or were part of a social blogging platform like Tumblr) was that our web site did not sit within the same network- i.e. it wasn't on Tumblr. This meant people had to 'up sticks' and come into our space. After reading Charles Leadbeater' *We Think*, and James Suroweicki's *The Wisdom of Crowds*, this creation of a space that you bring people to can work, but it requires champions- and a lot of work nurturing the community. Facebook didn't start spontaneously; Mark Zuckerberg and his colleagues created a space and had early champions who worked hard at the community.

Because we did not have a strong enough link with the bloggers we contacted, and because statistically we had contacted a small number, nobody came and used the site in the way it had been hoped. This also meant that we couldn't build up a champion (or champions).

Assuming that you're wanted

One assumption that we made was that people would want to talk to us- or that they would want to get on board with some design work. This assumption was built upon the assumption that when someone is 'more engaged' that that 'engagement' might mean they were willing to participate in co designing with us. However, someone who is 'engaged' and blogging might be blogging & sharing for themselves; they might not want / need to take that action any further. A well-kempt, regularly updated blog is not necessarily conducive to participation.

This idea goes further – after not succeeding in getting a good response from bloggers, we posted a call on certain Facebook walls, but were deleted by the moderators in one instance, and ignored by the users in another. The feeling was that people within these communities acted much like the bloggers, in that they perhaps shared for themselves, and that this level of participation among themselves did not necessarily mean that they wanted to participate in anything further.

Had the prototype been completed sooner, then iterative testing with people like Tony & Sarah from a much earlier point might have yielded better results here- however since we had not 'failed early', there was not enough time to make a change and use the web space for it's intended purpose.

Real people, like

From the beginning, I had slight misgivings about a purely online approach; but this was before my reading and research around open design and crowdsourcing, and as

such can be put down to the discomfort felt when working outside of one's comfort zone.

I was pleased that we would be working with local support groups, and after Dan's exhaustive search for parent support groups extra to the NHS provided services, we found a (surprisingly small) number of groups meeting in South Yorkshire. Members of UCHD had been to meet RYDA before I had the chance to go along and meet the group- my first meeting was during a demonstration by a demonstrator from Roche, who was showing how the latest Accu-Chek insulin pumps work.

At the beginning of the project, we were meeting with the Rotherham (RYDA) and Barnsley groups separately, and after a successful meeting in Barnsley where we had a productive design session the suggestion was made that we could combine the two groups for design workshops- that was very much welcomed as an idea.

Personally, I feel that one of the chief positive outputs of this project (irrespective of it's academic significance) was this ability to aid the networking of these two groups of people.

Reappropriating the website

Since the website was not successful in attracting people outside of the support groups, the website attempted to facilitate the discussions between the design workshops. However, this proved to not be the case, and the website was underused. However, much of this reappropriation work was done after I had left the project and returned to my PhD, as to the reasons that people did not use the website, it would be wrong for me to speculate.

Overall reflections – conclusion and summary

While on the face of this, 'phase zero' might look like an expensive disaster, this is not my belief or intention with this document. It is easy to look back on a project and with the benefit of hindsight see exactly why a project didn't reach it's full potential.

Chiefly I feel that a communication breakdown between the design & programming efforts (which should never have been separated as much as they were), and a delay in recognising that more programming capacity was required caused a terminal delay in the prototyping process. One way that I feel this could have been mitigated is if all people involved in the project agreed to work in the office on particular days, and participate in the open, free-flow of conversations over the course of the working day. Meetings and lists have a definite place in the process of running a project- but they make very poor substitutes for the open-office atmosphere required (especially in the early ideation stages) of a design project.

As a knock-on effect to this, the prototyping process was too drawn out- we had no early fails, and therefore no opportunity to learn and iterate at a quick pace.

Had we been able to fail early with the bloggers, Facebook groups, and Getting Sorted, we could have perhaps found other ways to engage a disparate group of people, and we might have arrived at a solution that was more compelling for the support groups.

We had precious few sources to fall back on to show how such an effort of crowdsourcing might work. I feel that I have particularly sharp hindsight, since my work on 'phase zero' preceded my reading on open design, and the work I've done on trying to understand how to build these sort of open, or crowdsourced systems (Leadbeater 2009, Suroweicki 2004, Press 2011, Abel et al 2011, Keen 2007, Nambisan & Sawhney 2010, Chesbrough, 2006...). As such, I feel that while 'phase zero' had a lot of difficulties- these are powerful learning points, not just for me and my PhD, but for us as UCHD as a whole. The work done on trying to make the process of informed consent more transparent and streamlined was a really important first step; and working with the adolescents at the Source developing novel design workshops is a great output.

Finally, we recognised during our conversations with RYDA and Barnsley that the participants were ready to dive into 'phase one'- and redesign the service. Perhaps while 'phase zero' was a noble effort - trying to 'engage' the 'unengaged' – the point was too subtle, and ultimately lost. This was especially apparent when explaining the project to Tony & Sarah; the distinction was too subtle.

AIR

Thoughts and work to date | AIR

This reflection begins with a summary of the preparation work completed so far- and the underlying assumptions that have shaped the way this preparation has taken place. This work covers the opening three weeks of the project – from the first invitation sent, through to the first welcome pack/TKUID. The invitation was accepted on the 20th February- the first day of the project, and the participant has been away for a holiday (1 week) during that time.

This work kicked off in early February 2012, after successful completion of the RF2.

Last year (15th November 2011) I contacted Martin Wildman, one of the two Consultants in charge of the Cystic Fibrosis ward here at Sheffield Teaching Hospitals Trust, to discuss the plans I had for the PhD. They were for the running of two concurrent projects- one co design and the other open design. However, after the RF2 this was changed to a single case study. The visit towards the end of November meant I got my first look at technology like the Acapella, and the nebuliser.

Assumptions

These are the main assumptions in the project- the ideas that have come to shape the way that this project is viewed by me as I work. For instance, the main assumptions are:

1. That this will be an interesting and engaging way for people to participate in the design process
    a. People will want to participate... if I have a *champion*
        i. Assuming the lessons learnt from Diabetes Phase Zero are applied
2. The process will come up with some novel concepts
3. That cultivating and sustaining activity will be hard work (Suroweicki, 2004)
    a. The correct tools should be employed – Suroweicki suggests Wikis
4. In order for people to engage and work with me in this, the production value of the work must be high
    a. People must feel welcomed into the project, and that the work is serious
5. The right tools need to be supplied to enable participants to express their ideas
    a. Or, that tools need to be supplied *at all*

b. These tools are an extension to the idea of *Toolkits for Innovation and Design (TKUID)* used in Mass Customisation
c. These tools are comprised of a physical aspect, *and* software
    i. Pens & 'traditional' design tools
    ii. MineCraft Print & SketchUp
d. People will find creative reflection difficult-

People will want to participate

From the diabetes reflections from working on the Phase Zero (P0) work last January, there were certain assumptions that were made which crippled the project. Chiefly, the idea that a well designed space would act as a big enough draw for people to participate was false, as was the notion that people who have diabetes are a homogeneous group to which labels can be applied. These two assumptions propagated further assumptions; the idea that people wouldn't want to talk to us or participate didn't occur, or that because a person posts their own thoughts and content on their blog then this would directly translate to them posting content on our site.

As such, these hard lessons have been carried over into this case study. Although research into other people's lives with Cystic Fibrosis (CF) has been made easier by looking at other people's blogs, this was not chosen as the default mode of recruitment. One thing that was mentioned time and time again in the diabetes P0 work was the need for a champion, someone who was sold on the idea of the project and who would participate. This was lacking in diabetes.

In searching for a person who might be amenable to participating in the project, a person known to another member of the UCHD team (Mark Fisher) was identified. This person is over 18, and has CF. This person has also posted videos on YouTube describing their lived experience of CF and had expressed an interest in participating on a project.

Tools and prototyping

Another problem with the P0 work was the difficulty with which prototypes were created- there was a feeling that in order to control the look and feel of the space, then a custom-built solution was required. However, this proved to be expensive and problematic. This project relies upon existing platforms that can be modified to suit the work. As such, the main space for work runs on the Ning™ social-media platform, and the website showcasing the project was created with Adobe™ Muse software. It is worth noting that both of these platforms allow for a professional look to be created, while allowing the functionality required to support design activity. In order to facilitate the creation of prototypes, a MakerBot™ Replicator has been purchased, in order to effectively and realistically build ideas that come from the participants.

However, work is required to effectively enable the participants to compose their own 3D CAD models.

TKUID

In order to allow the participants to develop their ideas, *Toolkits for User Innovation and Design* are required. Traditionally, these are software portals that allow customers to choose a combination of manufacturer-selected modules that can be arranged into a specific combination that is then produced and shipped to the customer. These tools allow the customer to imagine their own interpretations of products- but as von Hippel suggests, these could be used to allow the customer to design their own products (though still using a manufacturer's own modules). The development of a 'design toolkit' is new (or, appears this way with the research conducted so far). There are questions to address- can a design toolkit effectively allow someone to communicate their ideas? Can it allow someone to creatively reflect on his or her own situation? (in the same way that LSP is able to).

Changes & Feedback

In this first section, the stock website and Ning network were created, with tweaks to mean that they shared the same branding across all of the spaces- colours, fonts, etc. I expected the first participant to have something to say about how the space looked- but there was no comment past the initial agreement that this looked good. This is a shame, since I was hoping for a more critical response to the space- but the branding, colours, etc are deliberately not fixed – and I shall add a blog post to suggest that people come up with ideas to make the space seem a bit different, including a name change.

The static website that is used to describe the project has been revised a few times from feedback delivered by the UCHD team. This website acts as a landing page for people to be directed to – for more information about the project, etc. The changes were cosmetic, or related to content; how well it reads, whether it's clear, etc. This page was created quickly using Adobe Muse, since I lack the knowledge required to code a webpage (and it only needs to be a quick & easy site). This is currently hosted by Adobe, but will probably have to move due to the free trial period ending at some point. Currently, the URL to access the site is:
http://airdesignspace.businesscatalyst.com/index.html

TKUID

The first TKUID was created in this period. Initially, I decided to use the 'toolkit' metaphor and try to find a cheap metal toolbox that could be repurposed. This proved fruitless, and so I moved to trying to find a plastic toolbox. While there were several variants that could have been used, the cheapest was £3, and the cost of *n* multiples of TKUID rendered this an implausible option. Aesthetically these cheap plastic toolboxes were low quality- they did not convey the aspect that this is a project to be taken seriously and to be excited by. This led to another idea of toolboxes designed specifically for children, made from wood. Having had one of these miniature toolboxes as a child I felt that these could be repurposed into a fun, but also charming toolbox- using laser engraving/cutting and the University workshop features. However, these sets proved to be too costly to buy 'off-the-shelf', and too time consuming to produce by hand. After a brief think about other wooden containers I came across different producers making wooden wine bottle carriers, and also trinket boxes. This solved the issue of having to produce a wooden toolkit or box, but introduced a prohibitive cost- the cheapest wine bottle box was £7, with a further £7 for delivery (free delivery was available for large volume purchases). This idea, while being aesthetically sounder than using plastic toolboxes echoed the problems encountered with trying to build a bespoke P0 prototype.

After discussing the problems of developing the TKUID with other members of the UCHD team, I was advised to talk with Peter MacQueen from Design Futures' packaging to see if there was a solution using cardboard that could be used. This had the advantage of being both bespoke, and low cost, with the benefit that the 'E' flute corrugated board has a pleasant look, and a satisfying feel when used with proportionate shapes. Peter was exceptionally helpful, drawing a box net for me as a first attempt. Initially, I conceived the TKUID as a 'chocolate box' type of structure, containing a 'Really Useful Box' branded plastic tote container containing the stationary tools- and a Moleskine notebook.

The decision on the type of stationary to include referenced the tools that are mentioned on sites like Tumblr, and Core77. These sites propagate the notion of what a designer is, while also promoting the different tools that are seen as cliché- Moleskine notebooks, Sharpie pens, Copic markers, etc. Therefore, the tools chosen for the TKUID were:

- Staedtler colouring pencils
- Staedtler eraser
- Staedtler non-permanent black outliners
- Staedtler pencil sharpener
- Derwent HB sketching pencil
- Derwent H sketching pencil
- Derwent B sketching pencil
- Sharpie twin-tip permanent marker
- Post-It notes
- Moleskine sketchbook

Cheaper alternatives could have been chosen, but it was felt that this would have had a detrimental impact on the way the tool is perceived. This toolkit serves as a welcome pack, and it is perhaps prudent to think about other tools that one might require to work in a 'designerly' way – either on one's own or as part of a structured design session. For instance, in storyboarding it might be necessary to use figures to pose, with speech bubbles in a comic strip style. This could be photographed and printed, using a Polaroid Zink printer perhaps- as these work well with mobile phones and laptops. However, this is a £40 item- too much for an initial package to be sent to a participant. However, it might be feasible to have a 'menu' of different toolkits that one might borrow to work with, and then send back... like a lending library.

At the minute, the design toolkit/TKUID/welcome pack makes no provision for 3D CAD file creation. This is something that I need to consider – and I don't believe the right tool exists yet (neither does Bre Pettis – he said so during the Power of Making symposium last December). However, if Cody Sumter and his colleague develop a user-

friendly piece of code to use with Minecraft Print, then this could become more of an option. Google Sketchup is perhaps the best bet – but we'll have to see how this goes.

Ning

The site was created using the Ning 'Mini' package, which gives 30 days free, and then a £20 per annum charge for running a social network with some unique branding. This site has some very basic functionality, but it served as a base from which to garner opinion.

This site was created, and the appearance modified. The appearance was crucial, since for this project to work there ha to be a high level of production throughout. As such, the site was branded by myself. In naming the site, I wanted to choose something that was unconnected to cystic fibrosis, or any other chronic condition. I wanted to avoid people making assumptions about the space or how it would be used. As such, I wanted a name that embodied the following attributes- the same attributes that sharing ideas might have:

- Flexible
- Intangible
- Colourless
- Important

I decided on Air, as this is a noun, and can be used eponymously to refer to the site (e.g. '*Have you logged into Air yet?*'). The name is intended to reflect the degree of freedom that people have in publishing their ideas to the space, that it is a flexible medium and one that is also malleable. IT fills the shape of the container it is held in, even escaping from it under the right circumstances.

This initial creation and modification can be considered the ***Alpha*** launch; the basic functionality is created, but it needs content. Some initial ideas to populate the space with to act as a catalyst for ideas and discussions.

I had wanted to have a number (five) MakerBot 3D printers available to ship to participants, to act as incentives but also to assist in the creation of products. However, this option was far too costly to implement – also, the issues here are the technical support (although MakerBot's support is pretty good), and the fact that while reliable, the support required to keep them all running is an unknown quantity. Sadly, the budget doesn't stretch to sending out 3D printers. If this was a project being run by a Pharma / Medtech company though, then this might be more feasible – it might also engender a network of people to form around the product / service offering they produce?

Week Beginning 12th March

So far, participant #1 has had the TKUID/welcome pack for a week. Here was the feedback from receiving the package:

> Hi Matt!
>
> Yes I had a fantastic holiday thank you, feeling loads better for the fresh mountain air and exercise!
>
> The welcome pack is fantastic, it really inspired me and gave me itchy fingers to get drawing, designing and creating idea's! The sketchbook is an ideal size to easily carry around with you if you so wished and the variation of pens and pencils is fab! I was thinking, on air, if there was a section to scan and upload your drawings/diagrams so people can look at them and help to develop them, bouncing idea's off each other ect, as it is always helpful to have visualisations of idea's as well as written descriptions...everyone imagines things differently! The pack fitted through my postbox fine too!
>
> So overall fantastic work!
>
> Holly

This feedback is positive- and a little expected. One assumption is this it will be difficult for people to criticise the tools that are presented to them, because they might not feel comfortable creatively reflecting on them- or they see them as being 'too complete'- they aren't prototype-y enough.

The toolkit fitted through the participant's letterbox perfectly, although it seems prudent to reduce the dimensions slightly to accommodate older-style letterboxes. The tools will remain unchanged for now, until more data from participants becomes available.

This week has seen me email the participant to try and organise some 'design time' in the space, but as yet I have not had a reply. I will chase up the participant on Twitter.

In the mean time I am going to reorganise the space, cutting out some of the links, and neatening up the look. Also, I am going to sketch some ideas, and put them into the space too. This should create some ideas to bounce off.

Week Beginning 19th March

This week has seen an important step in the development of the case study. I have been in contact with Holly, and have also had an all supervisor meeting with Paul and Andy (more on that later).

I arranged to meet Holly in the Air design space to discuss the first steps of the project. We also tried to arrange another time to meet online and design some things. During the chat, we discussed the ways that ideas might be posted to the site, and the necessity of getting the sketches and ideas from the sketch books in the welcome pack/TKUID onto the website. There were other operational things discussed, as was the general 'look and feel' of the Ning site.

I feel that the Ning site is as good as I can make it at this stage, and in order to develop the site further, this would require a significant effort on my part, or the hiring of a web developer to get some stuff sorted.

Holly recognised that it was important to invite more people into the space, and that this would be difficult to do with there being nothing currently in there. As such, we initially decided to try and develop some ideas for things that could go in the space... I would develop some ideas, and Holly would develop some more. These would be posted as a way for people to interact with some initial content.

I also discussed consent with Holly, and resent the physical consent information to her home address.

We worked out when we might be able to begin working in the site in a meaningful way, and Holly suggested that although she was rather busy up until the 29th of March (with college and such), she would have the 2 Easter weeks completely free for work. I decided to plan activities around this lull (making more TKUID, etc).

Meeting with Andy & Paul 22nd March

In this meeting, we sought to clarify the different objectives of the project, and see what shape the interactions with Holly were taking. Possibly the most interesting aspect of the work so far (with regards to the communication with Holly) is that Holly seems keen to invite people and act as a community champion without much guidance from myself. For instance, it was Holly's insistence that she could contact people to extend an invite, via Twitter and the Cystic Life social network.

This eagerness to act in this capacity means that Holly is acting more as a co-researcher than a mere participant of the work. This is exactly the level of interaction that James Suroweicki talks about being necessary to grow a community in the first place. This movement from one type of participant to another is interesting- completely without

pushing, Holly has become keen to engage in a recruitment role. This suggestion was her own, in the chat session that we had on the 21st March (yesterday).

I have also met with Helen Turner to try and secure some sort of support for prototyping fashion articles in the SHU fashion department, after discussing with Holly that this appears to be something that she would be particularly interested in.

This now means that there is little that could not be prototyped here at SHU. I have access to 3D printing (MakerBot, FDM & Zcorp), wood, meatal, plastic and now fashion prototyping.

Another issue that was discussed in the meeting was the practicality of running design events to kick start the process. These could be organised over a short period, and potentially run like a Threadless Tee-shirt promotion. This might mean that there are incentives to participate, beyond simply having a go.

The format might differ even with this approach though- so, the activity might run over the course of a week, rather than simply a 24 hour period. I could find partners for this activity; medical product developers seem like idea candidates, but this should be carefully thought through before any potential partners are brought in.

The progress of the first case study has the potential to become slow- the momentum must be kept up with Holly, and it was considered prudent to begin to find other sources of recruitment. As such, I'll look to contacting the organisers of existing Cystic Fibrosis communities to see if there are any opportunities for collaboration. I will also contact the cf trust here in the UK. Failing these approaches, I will contact CF support groups, and contact Dr. Ade Adebajo about using PPI contacts.

Week Beginning 26th March

Following last week's activity, I decided to make a batch of 5 TKUID in anticipation of new attendees to the web space. This week has also been a low-point in communication with Holly. Holly mentioned that she was busy until the Easter break with college and family, so this is not unexpected. I decided to use this time to make more TKUID.

Week Beginning 2nd April

No contact from Holly.

I have made 5x TKUID ready to be sent out to people who join. It's becoming apparent that I will need to develop other sources for recruitment.

On the 4th of April, I contacted Cystic Life directly with an enquiry about possibly recruiting from their site. I received a reply on the 5th of April. Ronnie from Cystic Life was very keen on the idea for the project:

> Matt -
>
> I appreciate the email and I've very interested to hear more about what you're doing. I have CF myself and have thought of various medical products over the years that would make my life easier. Maybe we can hop on a call sometime next week and I can hear more about it.
>
> After the call, we can decide what role, if any, CysticLife can play in promoting this project.

Period between 05th April – 03rd May

Initially, I assumed that the community at Cystic Life (CL) would form a recruitment bed. However, Ronnie was obviously and understandably cautious for the CL community- since they have seemingly had occurrences in the past, which have damaged the members, or integrity of the community as a whole.

As such, Ronnie volunteered to come into the space and have a go himself. I called Ronnie on the 12th of April in Arizona to explain the project, with the aims, and the processes involved. Ronnie thought that the whole thing was a good idea, and as such agreed to take part. As such, on Friday the 13th I posted a welcome pack / TKUID to Ronnie in Arizona. This took about 10 days to arrive- during this time I edited the AIR site, getting it ready to be used for some sort of collaborative design effort; to populate the site with some ideas ready for other people to come in.

Beta Launch

The edits for the site included the renaming of some elements, and also adjusting the graphics that were used as part of the identity of the site. These were based on recommendations from Holly (before she ceased communication), and also the posting of the initial idea from Ronnie (that wasn't part of the work created with Holly in populating the Alpha site). Ronnie posted the first idea originating from a participant on the 3rd of May, under the heading 'Treatment Cabinet' in the Design Forum of the site:

> So as with many of you, my treatments (ie Vest and compressor) are out in the middle of my floor by my desk. I always thought that it would be nice to have a "treatment cabinet". It could be made out of would or plastic. It would fit the Vest in the lower portion and then have one or two pull out drawers. Ideally, one of the upper drawers would be refrigerated for any med that needed to be kept cold. The big bottom section that would enclose the Vest would have a large door to access it and the Vest would be put on a sliding bottom for easy access. There could be an additional slider to hold the compressor. Of course in the back would be holes to run all of the electrical.
>
> This may make no sense at all. I'll have to get back on to sketch something out.

Interesting to see with this post, that Ronnie is continuing the theme of not challenging the very nature of the treatment, but in fact the aspects of which fit into his life. This will be interesting to see whether this bears out in the posts made by other members of the community, and what other ideas come from this.

Initially, my response as a co-designer was to get the wrong end of the stick- as in, I proceeded to work on aspects that were 'window dressing'- I was more concerned about cable storage and making the system modular that I inadvertently missed the point. For instance, I initially posted the following:

Reply by Matt Dexter on May 3, 2012 at 18:42

Running the electrical cables could be a pain- there are some really nice examples of things that hide them away though. This computer by BMW design has all the cables and stuff in the thin bit on the right, with all the components jutting out:

And this cable trunking is pretty neat:

I don't know whether this is maybe worrying about the detail before we've thought through some more fundamental bits though?

▶ Reply ✎ Edit

Which was followed by Ronnie's comment:

Reply by Ronnie Sharpe on May 3, 2012 at 18:44

Yeah, the wires would be the least of my worries :)

▶ Reply ✉ Message ✎ Edit

While humorous, I felt I needed to apologise, or at least acknowledge my error:

Reply by Matt Dexter on May 3, 2012 at 18:46

Ha- trust the designer to obsess about the detail before getting the fundamentals! I'll have a bit more of a think...

▶ Reply ✎ Edit

Reply by Ronnie Sharpe on May 3, 2012 at 18:49

That happens to me all the time with websites; I understand.

▶ Reply ✉ Message ✎ Edit

This exchange was useful though, as it set the tone for the discussions in the site. I have to learn just as much about myself as a designer and researcher, as I do about Ronnie's life with CF. This mutual learning about situations is a hallmark of 'genuine

participation', and how this is fostered in all of the co-researchers (or, co-designers) is an important aspect of this exercise.

This beta launch of the website meant that the ideas were kicked-off, and there was a genuine dialogue between Ronnie and I in the space. However, this represents only a *collaborative* effort, distributed co-design, rather than open design. The community needs to grow, and with more people in it, then there will hopefully be more people to develop ideas from.

PPI / Involve

On the 6th of June, I also signed up for the People In Research (PIR) INVOLVE site, and posted a call for people to come and participate in AIR. It was my hope that people would be able to find my case study who had volunteered for other Cystic Fibrosis research. However, this has so far proved unfruitful. This might be because of the nature of PIR involvement... it's usually done to help define a research program, rather than recruit to a project. Dave Waddington approved this action on the 30th May (thus, approaching PIR INVOLVE and posting a call had ethics approval- as have all steps in this process). This has yielded no results in attracting any new members.

Recruitment of extra participants is proving difficult.

3rd May – July 12th

This initially appears to cover a large period of time. However, the activity undertaken during this time was a back-and-forth exchange between Ronnie and myself about the treatment cabinet and to a lesser extent the PocketPocket (the second prototype that came about from discussing the pre-Alpha and Alpha work).

During this time, I have been gently trying to suggest that we invite more people to AIR- I don't want to scare Ronnie off, and I do not want to offend him by making him think that I'm only after his contacts... so to speak. I emailed on the 14th of May (from within AIR):

> From Matt Dexter to Ronnie Sharpe
>
> Sent May 14, 2012
>
> Hi Ronnie,
>
> I hope this message finds you well. I'm really pleased that we've managed to progress and have some good back-and-forth on the forum, I'm really enjoying it. I'd really like to invite another couple of people into the space, so we can broaden out these conversations a bit, and see what other stuff people come up with.
>
> Do you have any people in mind at all? I have 4x welcome packs ready to go, but could make more if needed. I've sent a couple of invites to people in the UK, but I'm waiting to hear back on those.
>
> Let me know what you think.
>
> Cheers,
>
> Matt

I received a reply on the 16th of May:

> I'll think on who we should invite over. I'm on a mini vacation right now so my work schedule has been a bit sporadic. I'm enjoying this as well.
>
> Ronnie

I have not included this correspondence to seem petulant, or even aggrieved that Ronnie hasn't invited anyone else (yet), more to highlight that I am struggling to find more people to participate. Currently, this web space is an excellent example of participatory design in an online space, but there isn't much 'open' about it. That's partly to do with the 'open access but not open door' policy (which will need to change at some point... once the site is out of beta), but also because I (necessarily) am dealing with gatekeepers to other communities, and this requires tact, and discretion.

It was decided that instead of creating a whole new piece of furniture from scratch, that we would instead focus on developing a modular container that would act as an insert to an existing piece of furniture. However, we needed some form of furniture that this modular container could fit into, and as such we decided that IKEA furniture would be the system used. It is worth noting that the initial suggestion for the use of IKEA furniture was made by me, rather than coming from Ronnie; although this only arose as a consequence of Ronnie taking the initial step of talking about furniture. As such, this seems to represent that a *combination* of designer/non-designer working arrives at the best ideas? This seems to chime with Helena's PhD work.

Reply by Matt Dexter on May 4, 2012 at 18:06

Ok! I've had an idea. How about an insert for existing furniture? Maybe Ikea furniture? It's standard sizes, and some of the stuff looks ok:

Ronnie provided the details of the vest system that he used, and I produced on his behalf a prototype made from Plywood that would be shipped out to him for verification.

This method of prototyping is slightly problematic, since Ronnie is not making the prototype himself, and therefore not learning any new skills to empower himself as a person living with CF; to put it another way, he is not able to make an impact himself in this context, on his own day to day with CF. However, a slightly less pessimistic way of looking at the situation is that by participating in the process, Ronnie is empowered to make a change in his situation by proxy; that is, he still ends up with the goods, just via me rather than his own agency (due to circumstance- not being able to give him a MakerBot and the time to learn to use it).

The Summer looks like being a difficult time to engage in any making- not least due to the reduction in staffing at the University workshops for summer, but also the fact that Ronnie summer is the time for holidays and such. There were other aspects of the idea that required some thought, as Ronnie had suggested that a portion of the cabinet be refrigerated- this sort of problem requires some input that is beyond my experience –

I'll have to see how this work develops and whether I need to get someone like Ben Heller involved. A cabinet was bought in June (before I headed away to the 24hr design challenge in Lisbon), and I began to prototype the cabinet insert in the workshop after the students had left for the summer. This prototyping work was a good chance to try and use tools available in a Fab Lab- for instance, not using 3D milling machines and other equipment that might be beyond a Fab Lab setting, but instead 2D CNC routers, pillar drills, and the like. This meant that the design had to be simple. One slight bugbear is that the university's laser cutters are not set up for cutting thick (>6mm) Plywood, which meant that the insert couldn't be made in the same style as a MakerBot 3D printer. Instead, the edges were routed out, meaning that an accurate box could be made easily using only a single machine available to anyone with access to a Fab Lab.

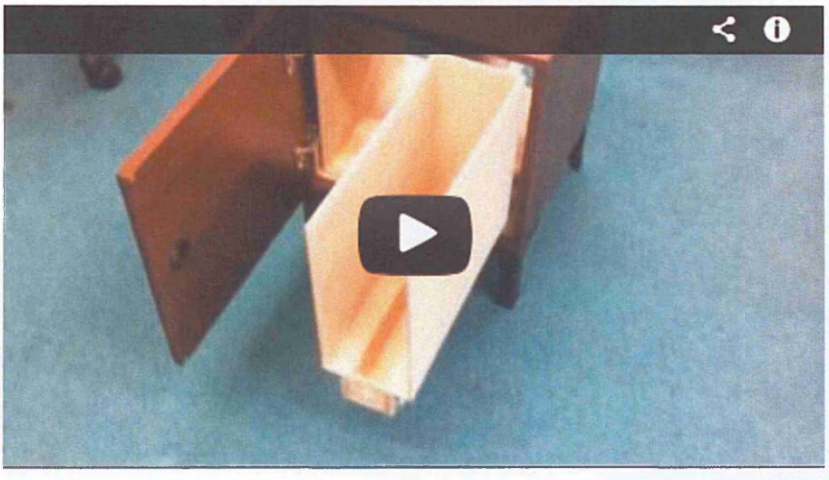
I uploaded a YouTube video of the prototype for others to see and comment on. The reaction was positive!

Reply by Matt Dexter on July 12, 2012 at 15:16

Ok!

Here is a first stab at the Treatment Cabinet idea. I made a Plywood box the same dimensions of the InCourage pump, then worked from those to produce a deep drawer that maximises the rest of the available space... Meaning that it extends out past the boundary of the Ikea bedside cabinet for easy access to the space.

I've bought some electronics to do the chilled part, but I'll ship the cabinet to you Ronnie so you can have a look close up. I'll do the chilled drawer and send it later.



▶ Reply Edit

Reply by Ronnie Sharpe on July 12, 2012 at 16:17

That's awesome man! Great job! I'm looking forward to demoing this thing.

Question: What's the best way to go about inviting someone to the group?

▶ Reply Message Edit

In fact, the reaction from Ronnie was so positive at this point that he enquired about the process for inviting more people to this web space. This led to the introduction of Amber, an undergraduate design student in Michigan who lives with CF. Amber was

invited by Ronnie, and this point marks the maturation of AIR to 'Release Candidate' (RC)[1]. The site was working, with ideas posted, commented on and other members being invited (and not by me).

Amber is an undergraduate design student in Michigan, and as such I would expect Amber to be excited to participate in a discussion about making stuff. I expect that Amber will be more comfortable in assuming the role of designer, and also facilitator- but it's interesting that Ronnie felt that Amber was the perfect fit for AIR, and out of the many, many people that Ronnie knows Amber was his choice to invite.

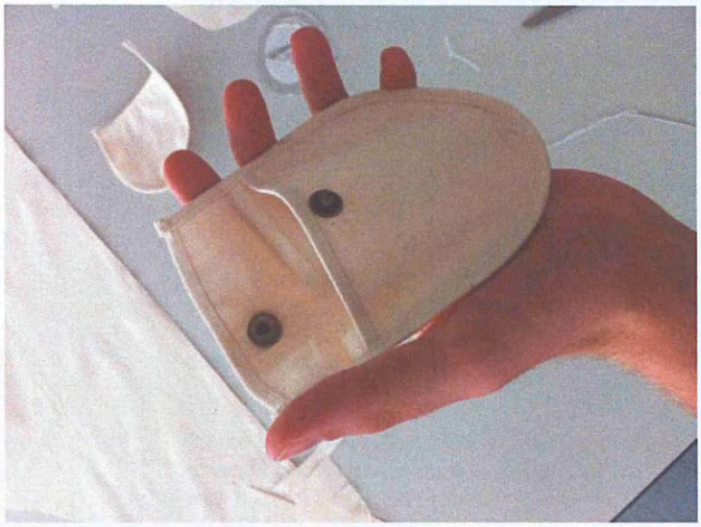
I don't see the fact that Amber is a design student as a problem- since in user-innovation not everyone has the capability, or even inclination to participate. Amber is therefore an archetypal 'lead user'- but also has the capability to be a champion, evangelist, and facilitator in AIR. It'll be interesting to see how this plays out.

During a similar time, (post Lisbon[2])- I arranged to have some help from Helen Turner the fashion technician to produce the first 'PocketPocket' prototype. This was a simple affair made from plain Calico, with a pres-stud closing. The dimensions weren't fully worked out, but the intention was to produce an artefact that might prompt some discussion. This was completed & uploaded to the web space on the 11th of July 2012.

[1] Using the coding parlance, Release Candidate relates to when a Beta piece of software matures to the stage that it's ready for launch. See here for more information.
[2] I participated in a 24hr design challenge organized by Ligia Lopes at FEUP Porto, and in collaboration with Julia Cassim, visiting senior research fellow at the Helen Hamlyn Centre, RCA. This was held in Lisbon, and while a lot of fun, was very challenging.

Reply by Matt Dexter on July 11, 2012 at 20:34

Ok, I have prototyped the Pocket Pocket in a rough material called Calico. It's just a basic cotton weave, but it demonstrates the potential of the design. I've attached a picture here:



Is this the type of thing that you were thinking? Is it suitable for the enzymes, or pills that you need?

▶ Reply Edit

Reply by Ronnie Sharpe on July 12, 2012 at 5:42

Wow, I think that's a GREAT start!!!

▶ Reply Message Edit

The development of this prototype has not been getting as much attention as the Treatment Cabinet; although I would assume that with such a small number of people participating then this simply reflects the fact that Ronnie has been more interested in an idea that he himself has posted, rather than one I originally posted to elicit some conversation.

The Treatment cabinet and PocketPocket were shipped to Ronnie in Phoenix, for verification with the artefacts that Ronnie currently uses himself.

For quick reference, here is Amber's first post to the conversation on this topic:

Reply by Amber Richter on August 10, 2012 at 5:23

You bet I am interested! =D

You guys have a great idea going here! Matt I like the idea of making the electrical part of the cabinet within it's self. If there is a way that you do not actually need to run any cords (other then the 1 to plug in the cabinet) that could be cool! So what I'm thinking is in each designated space you have a plug in. Also, what might be cool is incorporated into the drawer / space a place to wrap or organize the cord.

Ronnie, I have to admit it would be great to have a cabinet with refrigerating capabilities! I can't tell you how many times being a CFer with Roommates and shared refrigerator space has left me either worried about my medications getting spilled on or being the "special needs roomy" who took up more refrigerator space. =P As a student that cabinet would be a life saver!

So are these products aimed at those with updated equipment? The reason I ask is because if it is going to be built for a wide range of those with therapy vests, would you also like the size of the old dinosaur vest? =P I so happen to have one handy and I can get the dimensions for you. However, I am not sure how many are like me and have such an old style of the vest.The update of the vest is rather expensive, and not covered by all insurances. This is why looking at fitting the older style may also be beneficial.

This idea is impractical rate now, and a bit way out there (probably jumping the gun a bit)...How cool would it be to have an induction docking station as a cabinet, and all our equipment powered through induction! =D ...but man, that would be pricy! lol They teach us to dream big in school ;)

Here is a bit on induction capabilities
http://en.wikipedia.org/wiki/Inductive_charging

Since I am contributing slightly impractical ideas tonight (or at least not cost effective) I may need to come back to the discussion tomorrow =P (with pictures?)

▶ Reply ✉ Message ✎ Edit

Quite positive!

July was also the time that I posted a call to participate in the closed Beta of the site to my Tumblr blog (on the 6th). I 'promoted' the post on my site by paying a few dollars to have the post highlighted in other people's Tumblr 'feed', thus gaining a bit of publicity. The post itself was well received, having 16 'notes' about the post, and being disseminated fairly widely (based on the tiny number of followers my blog has). The post can be viewed here. As a result of posting this call, a guy called Ollie emailed and asked to join. As such, I sent Ollie a TKUID / toolkit, but to date Ollie hasn't posted anything on the site. Perhaps I should follow up on the introduction? Maybe I could email Holly too? Who knows, they might not be interested, but it might mean more people joining in with the conversations happening at the minute.

July 12th – September (end)

This looks like another big jump of time, although this portion of the development suffered from being conducted over the summer months; Ronnie was in hospital for some of this time, and Amber had the summer break from University and therefore was away for a significant portion of this time. Also, this was a heavy conference season, with trips to Waag in Amsterdam and PDC in August. Similarly, there was a trip to the ICDHS conference in Brazil in early September, and although all of these trips were useful and necessary for the PhD, they did mean spending time writing papers, preparing presentations and also a lot of reading.

Waag Society

This trip seemed a little impromptu, but it was organised so that I could meet with Sabine Reitenbach, who is a design researcher who specialises in open design and health (separately), using participatory methods in the healthcare setting. This was a productive morning, and we discussed lots of different aspects of open design, and how these might impact my work, and hers.

PDC

The doctoral consortium at PDC was an excellent opportunity to talk about the work being conducted in this first case study, and receive some great feedback. Essentially, the main points were about focussing on the audience for this research; who am I trying to reach? Does this research *have* to be 'all things to all people (in all disciplines)?' i.e. do I have to make this research translate *perfectly* into a positivist, empirical worldview for a profession such as medicine or engineering? After discussing this in the group, I would argue no. This work will be of enough use amongst fellow designers, and be disseminated amongst them for this to be useful enough.

Taking the framing from Action Research, then this means that I am seeking to alter *medical product design practice* by *doing* some medical product design. That's the audience that this work should speak to. Interestingly, there were a few PhD students who were doing different projects related to open design- some of the more interesting work was around how the design process is documented- how the people who participate in the process of collaboratively designing an artefact communicate the decisions taken. This has a bearing on my work – how in the **Design Forum** on AIR do people communicate their work?

From the back-and-forth between Ronnie, Amber and myself this has led to some long conversation strands in the **Design Forum**. This makes for difficult reading in a chronological order- also, conversations become 'nested' in a typical forum style, and then spread over several pages. This too interferes with the easy reading back of the

interplay between different participants. This work from PDC would seem to have a link here.

The doctoral consortium itself provided for some good peer-to-peer feedback; although the only main critique seemed to be the focus for the audience. The rest of the tools and discussion revolved more around the uniqueness of the inquiry.

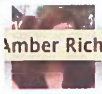
The rest of the PDC conference was very interesting – and also very useful. There were lots of papers about crowdsourcing, and also some more open source ways of working. These were obviously very relevant form my PhD, but so too were some of the papers on the periphery – some talked of the ethics that a Participatory Researcher should show- the *International Handbook of Participatory Design* was also launched at the event (sadly we didn't get a free copy). This manuscript has helped frame the write-up of this project- and it has also helped in the preparation for the EAD paper (and the ICDHS paper that I delivered).

For instance, there was one paper in particular from PDC that was of interest:

> REYES, L. & FINKEN S. (2012). Social Media as a platform for Participatory Design. In: *Participatory Design 2012*. Roskilde, Denmark 2012. Denmark, 89-92.

This project uses Facebook as the shared space for participatory design. The paper is itself very interesting, as it highlights some of the challenges to working in this way. Chiefly, the lengthening of the time required to undertake certain tasks- for instance, the pace of the online workshops was much slower, as people participated more at their leisure. After seeing the presentation, and also reading the paper, I have decided to conduct a 'Future Workshop' in the AIR design space. I expect that I shall find much the same as Reyes & Finken- that the workshops will not be conducted at the same pace. In fact, since the three of us all inhabit 3x time zones, then it is almost impossible to imagine a scenario where we would be simultaneously working. Therefore, I will allow for more time to be allocated to each particular stage, and have a 'workshop weekend'.

I blogged to all of the participants in AIR on the 21st of August about the possibility- wanting to give about a month's notice to the participants so that the work would be placed at a slightly higher priority than was usual. The feedback was good- although only Amber commented initially (see below).



Comment by Amber Richter on August 22, 2012 at 15:16

Amber Richter

I think that having us pick a time to dedicate to working together is a great idea. It is hard to make Air a priority when there is nothing scheduled. It's like a class that only has a due date at the end of the semester, the projects end up being a disappointment. Also, us working together towards a goal and committing to spending some solid time on it will also boost the progress of what it is we are working on, that way we can see that a difference is being made. The first weekend in September and the weekend of the 22nd are due dates for another project I am working on, so around those times I may not be able to contribute very much. Other then that I am on board. Exam week (school is starting next week) may end up being the same too. I might get quiet around here. Rate now I'm not sure when exam week is, so I'll just let you know when I know. =)

The workshop weekend was something that people could see themselves putting time aside for. Although, since I was away for the beginning of September (See ICDHS), and this was a busy period for both Amber and Ronnie (hospital visits, vacations, etc) I emailed both Amber and Ronnie on the 9th of October. This is covered in the next chapter.

ICDHS

The International Committee for Design History and Design Studies (ICDHS) conference was held in the first week of September. This was the conference that I presented the paper that was co-authored with Chris Jackson from Massey University in New Zealand. We have never met – instead, I posted a tweet asking if someone wanted to write a paper with me for the conference, and Chris offered. We wrote the paper collaboratively in Google Docs, and it was a really big hit. Also, it meant I got to go to São Paulo!

The paper was a great success, as was the presentation. There were some great discussions, and I made a great contact – Irene Maldini (design researcher from Waag in the Netherlands). The reference for this paper:

> DEXTER, M & JACKSON, C (2012). Making Space: The future places, tools and technologies for open design. Proceedings of the 8th conference of The International Committee for Design History and Design Studies, São Paulo, Brazil, 4th September 2012.

Workshop Activity, & going Google (October – November)

Currently, AIR is 'open access but closed door'. That means that people are free to attend, but they have to submit an application to join (or be invited). This is to comply with the original University ethics application from January 2012 (applied for during the RF2 – progression from MPhil to PhD status)... I have had to prove that the space would not harm those people who took part (to the best of my planning), and show that when people are given the option to take part they can either choose to be anonymous or visible. Thus far people have been 'consented' by signposting them to the static website that outlines the project (http://airdesignspace.businesscatalyst.com/index.html).

Once they have read about the project and wish to take part, information is printed and sent to their home address. This should be printed, signed, and then returned. So far, only Amber has filled in their form – I have asked Ronnie and Holly for theirs but Holly ceased contact (but left her posts online), and Ronnie has not sent his form. All three received printed copies of their entitlements (to leave at any time, taking their stuff or leaving it, and that they can be anonymous or visible), and had the information electronically- thus all were 'informed' before they took part of their own volition.

An 'open access but closed door' approach is not conducive to Open Design. So far then, the activities have been a novel approach to collaborative design- but not open. The proposed change to the site would mean that anyone could find the site, sign up and participate without me being a gatekeeper. An amendment was needed to change the ethics that I had set up with the University. I emailed an outline to the chair of the faculty ethics board, after meeting with him to discuss the proposal. This email acts as the 'paper trail' back to the ethics board, allowing for the change in status for the web space. This happened in early November, after the workshop weekend (described below). The email to the chair of the ethics board (6th November 2012):

> Thanks for taking the time to meet with me earlier and discuss the proposed alterations to the protocol for my PhD case study. As per your recommendation and further to our conversation, I thought I might outline the proposed changes here. Broadly, the site remains the same; the underlying architecture, and the participants will not change. The site runs using the commercial NING software for building social networks, which has built-in security settings, administration tools and the like. Currently, participants are invited through me, authorised and then can see, sign in and participate in the different activities (posing ideas in the form of pictures, video, sketches, etc). The change proposed is to allow for

members of the public to find, sign up, and participate by themselves, without requiring my authorisation beforehand.

There are a number of important points worth reiterating:

- The participants are recruited / participate in their capacities as **people**, not **patients**. This means that while a person who participates from the UK will certainly be a recipient of NHS services, they have not been recruited through those NHS services (or indeed, any other NHS services, personnel or at any NHS locations) and as such NHS ethics does not apply or need to be sought.
- I as the site's administrator retain full rights and ability to moderate (up to and including banning members) according to the 'netiquette' statement available to those who sign up to the site.
- The site can be made private again, if required.
- The current active members of the site have the opportunity to remove any information that they would not wish to share.
- The current active members have been consulted, and are happy for the site to proceed towards being an open site.

I hope that this clarification of the points we discussed earlier today is sufficient, but please let me know if you need me to go through anything again. I'm aiming to open the site up in two weeks time.

The reply from the chair of the ethics committee ensures that the process is complete:

Dear Matt

Thank you for responding so quickly and comprehensively with regard to the points raised in our discussion of the slight readjustment to your methodology.

I have taken the liberty of conferring with colleagues on the ACES FREC and am happy to say that, based on the reassurances you have given, we are happy to endorse this change.

Please keep a record of this correspondence for your files. Do let us know if we can be of any further assistance.

Best wishes

Dave

Professor David Waddington

Chair, ACES Faculty Research Ethics Committee

The toolkits that were produced for Holly, Oliver, Ronnie and Amber will not be produced for additional members that sign up after the 'opening' of AIR. This is because there is not the resource in the PhD budget to keep producing these items. Of the 4 that have been posted out, all have been well received, but there is no evidence to say that they have engendered or enriched participation in the space. For instance, Holly has left the space (I'm assuming for personal reasons), Oliver has not posted or interacted with the space since receiving his toolkit, and while Ronnie and Amber have both been active in the space neither has used the toolkit for the work. The toolkits were good gifts to make people feel welcomed (a success in that regard), but cannot be counted upon to enrich or enliven the participation. AIR, and the Ning™ platform it's build on are instead the primary 'Toolkit for User Innovation and Design'.

Future Workshop

This activity forms part of the larger 'beta' development of the site... the it's ready for 'prime time' (as a 'Release Candidate'), but in terms of research, this forms a separate activity in Action Research – it's a different Action Cycle.

The process requires that the participants are informed, and that they would have sufficient time to remove their content, or withdraw their involvement in the process. The site was taken live after the workshop week(s), as described below.

On the 9th of October I emailed both Ronnie and Amber about the Workshop activity, and how this would work. Initially, I wanted to save the date with them, as I wanted the work to be a priority for them (as much as each felt able). The email read:

> Hello Both,
>
> I thought I would drop you an email, since I don't currently have access to a web browser (a long story!) to log into AIR.
>
> I'd very much like to try and organise a co-ordinated weekend where we thrash out some ideas together; obviously there would be time-delay issues, but if we did it over the course of a weekend, then hopefully this should minimise that problem! I thought a weekend might work best, because it sets a distinct amount of time aside; it wouldn't spill over into the week... We're all busy people! The only issue for myself would be that I have a church service on Sundays for 2 hours... but other than that could be available!
>
> Another idea that I wanted to discuss with you both would be opening up AIR to be Google searchable... also, opening it up so that anyone could sign up- without needing to be authorised. This would mean that people could find & join the site for themselves. Of course, since you are both active on the site, I want this to be a collaborative discussion; not a 'top-down' dictation!

> Anyway, I hope that this email finds you both well!
>
> Kind regards,
>
> Matt

Both Amber and Ronnie emailed back and suggested that the weekend of the 27th and 28th (of October) would be good weekends to attempt a workshop weekend. As such, this was the plan. I emailed to confirm the date with both Ronnie and Amber on the 11th of October. Neither Ronnie or Amber (or the other two dormant members of AIR) added any input on opening the space up. As such, I enquired about the process (for ethics) with the chair of the faculty ethics board, and set that in motion (see previous section). On the 26th of October, I blogged (in AIR) about the structure of the weekend, as a primer for the event.

In hindsight, a couple of day's notice would perhaps have been a better length of time for this to sink in. The blog post is copied over.

Hello all.

I thought I'd add a short blog entry here to describe what this weekend's activity will look like!

There are some basic rules- nothing too terrifying I hope! These are to ensure that we don't loose any good ideas early on, since some of the best solutions come from seemingly crazy suggestions. So, here are the rules:

No idea is a bad idea. Even crazy suggestions are ok.

Constructive responses only; disagreements are fine, but don't shut someone down.

Everyone draws! Not all the time, but a picture is worth a thousand words; if you have an idea, a rough, scrappy drawing is better than a paragraph!

No solutions on Saturday! (we don't want to miss anything that might be valuable).

We'll be spending Saturday and Sunday working on some ideas. As long as you can be near to a computer or phone to reply & engage, that's fine (it's ok to go shopping, or have a coffee with some friends- just watch for replies!).

What will this look like?

We're all in different time zones. As such, we'll work to the last one (AZ - MST); I'll be up first (GMT), so will get to work posting some suggestions here. There's no need to stay up super-late; Any discussions that Amber (UTC) and Ronnie (MST) have I'll respond to on Monday (since I'm 7 hours ahead!), and that'll be the end of our workshop.

What will we do?

This workshop will be a way to come up with some new ideas. There are 3 phases:

Review & Research

Fantasy & Imaginative

Implementation

We'll keep these to a loose timetable, so that we don't get bogged down. So, Saturday morning (until about lunchtime) will be Review & Research, lunchtime Saturday until Saturday night will be Fantasy & Imaginative and on Sunday we'll focus on Implementation (but it's fine if we're still imagining new ideas on Sunday morning - sleeping on a topic is a good idea!).

Review & Research

If we were all in a room together, we'd put ideas on a Post-It note and stick it to a wall, so we could all see what a person thinks, and add our own comment; maybe grouping some comments together in a theme. Instead, we'll post comments below.

Post what though?

This site is all about coming up with devices that help manage CF. These can be anything; a better designed Nebuliser, better Enzyme storage, etc. However, instead of just trying to have an idea 'cold', we'll imagine a scenario. Our scenario is ***A day in the life.***

Post stuff you do that concerns your day. Post anything- even tiny details that you might consider insignificant matter. Short comments rule here- but include how you feel when you do that activity; and how CF makes an impact. Work chronologically; from when you wake up, to when you sleep.

My input here will be less to begin with; I'll post a small number of ideas based on my own research; but since I don't live with CF it would be wrong of me to assume. Use these comments as a starting point; something to disagree/agree with.

Fantasy & Imaginative

This is the fun bit! We'll take the comments people have put down, and together see which are the ones that have common themes. Then, we can all think of stuff- this is the point when anything goes. It doesn't have to be feasible, and it definitely can be impossible if you'd like!

In this stage, we're concerned with linking ideas together, or imagining how these solutions might be if we could have our way.

In this stage we'll come up with concepts- but these concepts might not be feasible; and that's totally fine.

Implementation

On Sunday, we'll try and see if we can take the crazy from Saturday (and maybe Sunday morning) and imagine some concepts that could be 'for real'. On Monday morning, I'll look through what was proposed over the weekend and post the concepts as different (separate) topics in the Design Forum (like the Treatment Cabinet, and Pocket Pocket).

We can then work on these at our leisure.

I'm looking forward to it - and I hope you are too! Just drop me a line if you'd like to chat about any of the particulars.

Matt

The initial response to this activity was worrying. Friday and Saturday there were no responses to the postings that I had made in the **Design Forum** under the new heading 'Workshop Weekend'. This was disheartening, as you may well imagine. However, just as I was finishing at Church on Sunday evening, Ronnie and Amber began posting ideas into the site. This was, as you can imagine, a relief. On October the 28th, Ronnie posted a topic in the forum as a summary for the ideas that were generated at the Workshop Weekend. This was unprompted, and is another time where we see Ronnie take the lead on promoting some aspect of the website that he finds useful / valuable. Ronnie has proven to be a champion to the site, and without his help, this research would not have been possible to the extent that it is currently. The post that Ronnie added reads:

> Thought it would be good to have a dedicated blog just for ideas....
>
> - Vest tube extenders
>
> - Smaller lightweight compressor with high PSI output
>
> - Enzyme dispenser that puts out corret number of pills with single push/twist
>
> - Carry-on insert specifically for CF equipment/meds
>
> - Continue working on treatment cabinet idea. Great start!

Interestingly, there was only a small amount of engagement with the original topic 'A Day In The Life'. I had expected there to be more storytelling, more reflection and a more structured design workshop 'feel'. However, there was not as much of this proposed as I had imagined.

Also, from the original reading, I had stretched the workshop from an afternoon (in a 'real', physical setting) to an entire weekend in the web space. This proved to be too little time still- Ronnie suggested extending the workshop over 3 weeks – with each week taking the place of a particular topic. 'Review & Research', 'Fantasy & Imaginative' & 'Implementation'. This worked better, with the topics listed above postulated in their own postings on the **Design Forum**. However, the momentum slowed down as the project progressed, seemingly as a natural pace as the work progressed, but also because specifically Amber had University commitments to attend to. Also, my work was too 'hands off'- upon reflection, I could have done more to chivvy people along.

This is the point when Amber began to take on a greater role in the web space. I added Amber as a friend on Facebook- importantly I did not see this as a breach of ethics, since so much of designing products together is about building relationships and empathising with others. As such, Amber has begun to take a greater role in advocacy of the web space.

November – December 2012

As per the introduction of the last entry, AIR is changing (has changed, at the time of writing). The access to the space is more open now, as it was opened up to be Google searchable in mid November. This also means that people who happen across the site can sign up without being authorised by me.

I emailed the 4 registered members of AIR on the 1st of November (Holly, Oliver, Ronnie and Amber) to let them know of the change in status. Emails sent within AIR are forwarded to the member's own email address. This seemed a more appropriate way of contacting the members, since Holly had left abruptly and Oliver had not posted. The email of the 1st November read:

> Hello all,
>
> I hope this email finds you well. Now that there is some great content in the web space, and the workshop weeks are producing more and more content, I'd like to open up the web space to the public. This is the real benefit of open design, and the whole point of this exercise. I'll open it to the public in two week's time... meaning that the '**open day**' will be the **15th of November**.
>
> If you have any concerns of queries about this, then I'd be happy to talk them through with you. Just drop me an email.
>
> Remember, that you are be able and entitled to leave the space at any time, as per the consent form that I sent out when you joined the project. Although, I of course hope that you'll stay!
>
> Please do get in touch if you would like to go through anything.
>
> Cheers,
>
> Matt

The email lays out the timeframe, and gives 2 weeks notice of the opening of the space (that it will be public, rather than private), and that they can leave at any time if they want. No one objected to the opening- in fact Amber emailed the next day (November the 2nd) with a positive response:

> =) Sounds good. I'm still all in. I'll try to get some more stuff up here soon. Thesis 1 just sent us spinning into 50 pages of ideation (is that a real word?) by Tuesday =P So I apologize if I'm delayed at all in getting work up here (especially drawings)
>
> Take care,
>
> Amber

The activity after the workshop weeks (which, as mentioned above somewhat petered out) began to slow down somewhat as Ronnie and Amber both broke for thanksgiving, and we all began preparing for Christmas. However, these two months were the beginning of the rapid growth that AIR has gone through. For instance, in beginning to actually develop some products, and see prototypes develop in an interesting fashion, I emailed Ronnie about recruitment- an email that I had sent a couple of times during the year previous that had not usually resulted in much. However, Ronnie responded positively- he asked whether I would write a post for his blog (which is followed by a substantial number of the Cystic Life community) inviting people to join AIR – this was tough to write, since it meant summarising the project in general terms.

As such, I wrote an introduction to open design, and why it might be of benefit to people who have cystic fibrosis.

This blog post resulted in the number of community members in AIR more than doubling over the course of a couple of days. This is a very exciting development! Every one of these new members was greeted by myself, with a short email thanking them for taking part, expressing the view that *any* contribution is valid (no matter how small), and inviting any questions or comments. These new members are currently not posting ideas, but they have joined in the week leading up to Christmas, and as such they might be (and probably are) quite busy with family preparations. They have asked a question or two, and this is where the site might end up having 2x functions (like the Coloplast *Innovation by you* site). These being:

- Product development
  This being done in 'secret' by Coloplast, in a VIP area. Rather than in the open for AIR
- Support
  In Coloplast's case, with their ostomy products – but also with the conditions people live with. Maybe AIR will naturally begin to function in this way?

Ronnie's community Cystic Life already performs this function, and I have always been keen to not impinge on this important function[3]. The support material, and introductions that describe AIR do not describe the site as having this function. The questions posted about other aspects of life with CF have been unprompted. This leads me to two questions about working in this way:

1. Is it a natural development that people in an online community will seek advice about their chronic condition in an online environment?
2. Is this the *assumption* that the web space (AIR) will perform this function?

[3] After all, who am I to breeze in and offer a place for people to congregate and share their hopes / fears / desires and support during their life with such a chronic condition as Cystic Fibrosis? This seems a fraudulent way of portraying myself, and the research project.

There is a subtle difference between these two questions. One is the *assumption* that *AIR* functions in this way; the other is that at a certain point the active members of a community are seen for their expert knowledge and begin to *naturally* take on this role.

Amber answering the commenter's question fulfils this first point, but since this was the commenter's *first* post, it led me to think the second.

Medicines and Healthcare Products Regulatory Agency (MHRA)

In order to begin to get a better handle on the state of regulation and the opportunities for developing medical products using Open Design, I contacted Neil Ebeneezer at the MHRA to discuss the opportunities and issues surrounding Open Design.

We met at the MHRA offices in central London on the 9th of November 2012. Here, we discussed how regulation might cover '3D Printed' medical products, and what this might mean for future developments. From this meeting, it appears that the current draft EU legislation would cover this work as a 'custom build medical product', with the person actually doing the *printing* as the manufacturer.

Therefore, if the person making the medical product from the plans were to be making a medical product that needed to be certified by a 'notified body' (i.e an entity certified for testing the adherence of the medical product to the standardised procedure) then this would be their responsibility. As the enzyme dispenser would be a 'Class I' medical product, then it should be enough for them to self-certify.

Since the medical products here are not being 'sold' or passed off as anything other than 'prototypes', this should not be a concern- however, if these are to be used in a wider setting, then they would need to be prescribed by a physician. It would be best then, to post these with a standard open source warrantee disclaimer for the time being, in a similar way to software licenses (this is of particular concern on a site such as Thingiverse.com, which is out of the jurisdiction of AIR).

Martin Wildman, CFTrust, and Ben Heller

Towards the end of December, I emailed Martin Wildman about the possibility of arranging a meeting to show him the work that had been completed. This happened after AIR had been taken public, so that Martin would be able to see the work that had been completed. I eventually arranged a meeting at the Northern General hospital for December.

During this meeting, it transpired that the unit was preparing an NIHR Program Grant to develop a system for logging the various aspects of CF management. For instance, they were already building some prototype equipment with data logging equipment to measure different aspects of CF self management, the data from these devices would be uploaded to a central website which would graph the data. This data, relating to

aspects of CF management that are currently difficult or impossible to visualise for the clinical staff or the patients will be collaboratively used to improve health outcomes.

Martin used the idea of 'the invisible being made visible'. There are obvious benefits for the patient, but also for the staff who currently have to rely on patient testimony to build a picture of a person's management regime. This can be patchy, even for a relatively 'engaged' patient.

Currently, the system has three areas for development- two are 'secret', since these are being developed with companies that would want to retain an option on the IP of the devices that come from this.

However, the third area currently has no development schedule. Enzyme dispensing has been recognised by the clinic staff as an activity that is not easy to record, analyse and inspect by either the patients, or the staff when reviewing a the self-management.

The following email was sent by Martin on the 12th of December 2012:

> Hi Matt,
>
> Quick question that you might reflect on. This may come to nothing and may be a project already taken up else where.
>
> We have been approached by a company to develop a box that allows pills to be carried conveniently in a pocket and to be popped out during the day so that enzymes can be taken with food. We would like this to be chipped so that timing of each tablet can be measured and downloaded.
>
> The pill box needs to be produced asap and prototype may need to be produced without funding and will be funded if looks useable.
>
> Have you anyone who can do this quickly ?
>
> Martin

As you can see, this email was pretty timely, as following the Future Workshop in AIR this was a primary focus for the members! I emailed Martin back to get some more information about this, and to see what the opportunities were.

On the 18th of December we had a meeting at the CF ward in Sheffield between me, Ben and Martin. This was where the bid for £10K from Abbott pharmaceutical might come in to test the new Creon Dispensers.

This development is really exciting, since it means that the enzyme dispensers that we develop will form part of the wider NIHR program grant... and the benefits that they should have could be measured. For instance, if we have a control group of people with the regular pot (from Abbott), and then another group with a 'chipped' dispenser designed in AIR, then we'll be able to measure the weight management (via the new website) and the data from the dispensers themselves. Thus, we could use this

evidence to *show* whether the dispensers are better or not. This could be a dynamite outcome for the PhD- I hope the timeframes match!

Ben Heller is an engineer and Researcher at Sheffield Hallam in the Sports engineering department at Collegiate Campus, in the Department of Health and Wellbeing. Ben has been collaborating with Martin on one of the 'connected devices' for the NIHR program grant, and as such is a great contact for developing the electronics and data logging for the enzyme dispenser.

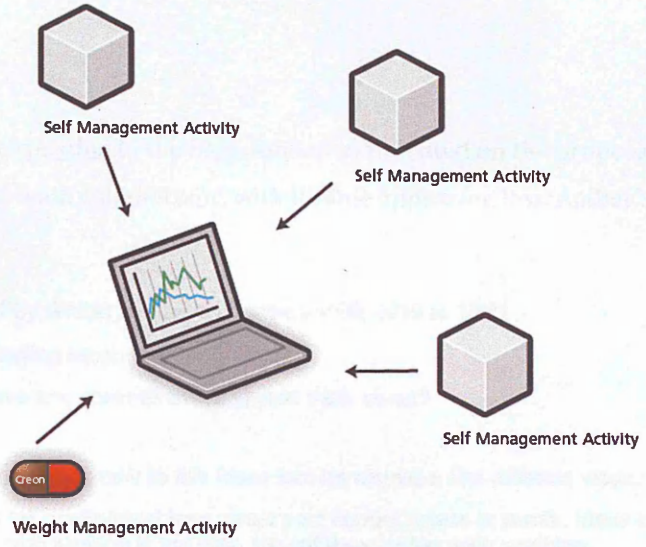
I have been trying to engage the CF Trust (national charity) for a while now with the odd email, but have had no success. I assumed that I hadn't happened across the most appropriate contact- and after discussing my inability to gain meaningful contact with them at my meeting with Martin (13th December), Martin informed me that the CF Trust undergoing a period of change internally. No more elaboration, but I gathered that I should not expect too much success from trying to contact them any time soon. Perhaps a good idea to try again once the project is completed? Perhaps even if there is a 24Hr Design Challenge at the D4H conference this year... my name is penciled in to organize / run this, so in all likelihood CF will be the theme. Perhaps this will be a good opportunity to engage the CF Trust.

Collaboration So Far

There has been a lot of work for the treatment cabinet so far, and the workshop weeks have proved successful in developing some ideas to take forward. However, the toolkits have not been used widely- or with any real evidence in the ideas that have been posted. This is disappointing, but as mentioned before, they were all widely welcomed and received.

Dispenser Development: Nov through Dec 2013 – Jan 2014

On the 20th December 2013 I posted a blog entry detailing the opportunity to design an enzyme dispenser, and a little bit about the project as a whole. This was really difficult to do, since I can't talk about some aspects of the project at all, so need to be quite vague. The opening of the entry is given below:



> Hello all.
>
> Last week, I had the opportunity to meet one of the heads of Cystic Fibrosis health services here in Sheffield, UK. We had a great meeting, and it seems there is a lot of crossover with what we are doing here in AIR, and a project that is going on at the minute.
>
> Essentially, a system is being developed that can log different aspects of CF daily management that couldn't be previously measured- this data is then used in consultations to better help develop strategies to self-manage, or for on-the-fly feedback.

The graphic details the system as much as possible without giving away the different aspects. The overall NIHR Program Grant is licensed with the other Pharma / Medtech companies in a noncompetitive license to enable the development without having them torpedo it by developing a competing system in parallel to launch as a competitor. In my meetings an discussions with Martin I realised that I was perhaps quite naïve when it came to contract negotiations with big Pharma / Medtech, and that business opportunities are seized upon- sometimes ruthlessly.

These discussions at the end of December led me to add an obvious Creative Commons license with a non-commercial clause. As such, the CC-BY-NC graphic is prominently displayed at the top of the webspace. This is to try andgive a small amount of 'protection' to the young ideas on the web space... this is not to try and 'close' the ideas off, more to try and encourage participation in the web space. The CC-BY-NC license seeks to enable the development of the ideas, but without people making money off of the ideas (who are not the original creators). This might be an overreaction to the warning given by the supervisory CF teams (and also the University enterprise service), but changing licenses is not difficult in the future. It also seems appropriate to try and 'play fair' by the collaborators who are pitching in their own time and resources.

Correspondence

Immediately after posting in the blog, Amber commented on the proposal. Amber by this time was the main collaborator, with Ronnie appearing less. Amber's response is given below:

Comment by Amber Richter on December 20, 2012 at 18:11

Are we starting broad then?

Do we have any constraints we should think about?

For anyone who is new to this ideas can be shared a few different ways.

First, just by posting text here about your current needs or wants, ideas or concerns. In brainstorming Nothing is too silly, too out there or too well, anything.

Second is drawing, You can sketch ideas of how objects can function or work, or what you want those objects to do. You don't need to think your drawings are not good enough as no one will judge you here.

Third is a thing we call use scenarios. This is drawings or pictures showing how you currently do things, or how you want to do things. Much like a story board these are images of you, or people (even stick figures) interacting with the Enzyme container.

Matt, If I'm repeating information you have already shared feel free to either delete this or let me know. Also, If I missed something please add to it!

Edit

Here we can see Amber really taking the role of champion, and providing information on using AIR to its fullest potential. There weren't too many people participating to the same extent (as Amber) at this point, but that hasn't stopped Amber from assuming the role. Here we can see here explaining the process that we might take. Amber even began to add ideas:

Comment by Amber Richter on December 20, 2012 at 18:19

Brainstorming:

For me I have several bags, backpacks and things I change out frequently when I travel even short distances. I usually forget my enzymes when the container I keep them in is "in another bag at home"

Could we come up with divices that are somewhat modular and can share information back and forth?

For example, I take enzymes at lunch via the container I keep at home in my kitchen. Later I am out for dinner and take the enzymes from the container in my purse. I cant remember if I took what I needed to for lunch, can the container in my purse tell me what I took at home? If so would this be helpful?

Overdosing: This happens when I take my enzymes, than forget within 10 minutes if I had taken them... does this happen to anyone else? I could see that a time record on the enzyme container may help with this.

Edit

Amber now began to add ideas in the comments on the blog, and these are right on point. The ideas are great – and derived *straight* from her lived experience. This is perhaps not the most complex of medical products (from my own reading, the dispenser seems to be of the Class 1 variety). The definition of a medical product comes from the EU Medical Device Directive (Directive 93/42/EEC):

> 'Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
>
> Diagnosis, prevention, monitoring, treatment or alleviation of disease, - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, - investigation, replacement or modification of the anatomy or of a physiological process, - control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means'

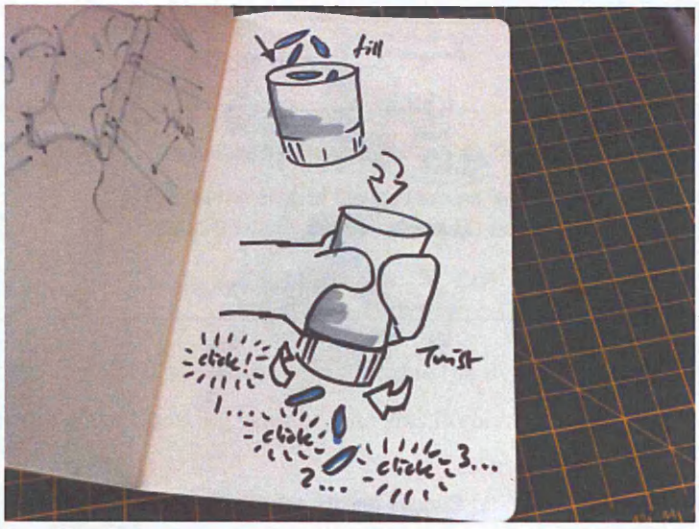
In this case, the dispenser is used for the monitoring and alleviation of the disease.

The discussions for the dispenser had begun on the 8th of November, with a provocation by me. These were some quick sketches to try and gauge a reaction to some ideas. I had no idea whether they would be received well, or used as the basis for other ideas going forward. I used the equipment that I had sent out with the original toolkits – I didn't want what I was doing to appear 'hocus pocus'... that is, I wasn't using any 'magic' equipment to get the sketches done. I also used very rough sketches too, to try and make people feel at ease with contributing some ideas:

Reply by Matt Dexter on November 8, 2012 at 12:37

Ok, first up.

Two ideas for maybe dialling the right amount of enzymes... no need to worry about *how* it might work at the minute; any idea is a good idea at this stage! This idea is a bit like the insulin pens that some people with diabetes use. Twisting the top adjusts the amount of enymes that are dispensed, and then pressing the top back in releases them. See what you think:



The problems associated with the tools available became apparent early on. For instance, the tools in Ning™ for facilitating discussions act like regular internet forums. That is to say, that they don't cope well with nested, chronological conversations. This is highlighted by the replies immediately below the initial post as above:

Reply by Ronnie Sharpe on November 11, 2012 at 4:52

Generally speaking, the enzymes are bigger than a Tylenol pill. I'm guessing by an additional 50%.

▶ Reply ✉ Message ✎ Edit

Reply by Amber Richter on November 11, 2012 at 23:36

I'm liking the push idea because you may be able to do it with the same hand that is holding the bottle, leaving the second free to catch the enzymes.

Size I believe may vary a bit between prescriptions (at least it use to). I couldn't find size info on Creon's website. Here are some pictures of mine next to midol (sorry its all I had) and asprin.

▶ Reply ✉ Message ✎ Edit

Ronnie's reply about the physical size of the enzymes being bigger than Tylenol (Paracetamol) is in response to a discussion that happened later, but due to a quirk in the way that replies are nested, the text appears higher up in the discussion than it actually happened. This might be 'user error', in that the reply might be 'better' placed

in the hierarchy if the 'wrong' reply button hadn't been used... but this then only serves to highlight the inability of the architecture to deal with complex multi-person discussions.

Early on in the discussions, we can see Ronnie and Amber laying out some general specifics for the dispenser- some guiding principles for the first prototypes. These were different from my assumptions – I gathered that the feeling would be for a device that stored everything, all the time.

Reply by Ronnie Sharpe on November 15, 2012 at 13:42

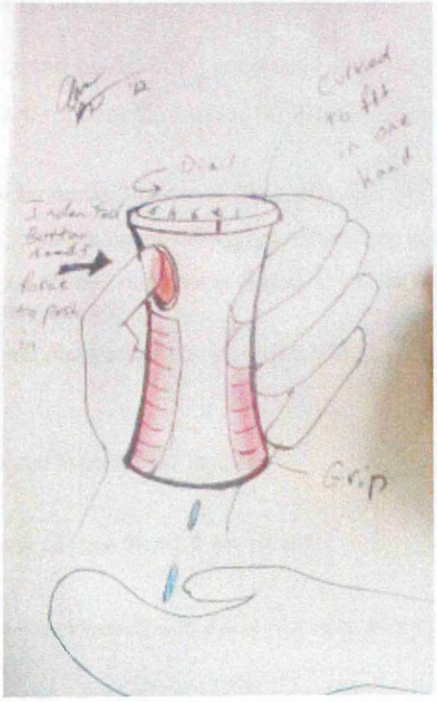
I think the size of the actual unit is more important than how many pills it actually holds. I take around 30 enzymes a day.

▶ Reply ✉ Message ✎ Edit

These sorts of discussions help to frame the overall design direction, so even though Ronnie wasn't posting sketches, he was involved in the process.

Reply by Amber Richter on November 16, 2012 at 17:24

I sketched a rough idea of where the button might fall if you wanted to operate it with one hand, sorry its a bit hard to see. I'll scan it in this weekend and re post it.



▶ Reply ✉ Message ✎ Edit

The level of design here is consistent with early-stage prototyping- there is little detail of the inner workings, but instead this deals with the overall function... it's an idealised outcome, with a preferred function (dial the correct amount, then dispense).

Even here in mid-November though we see Ronnie discussing the usefulness of a 'one pill per push' notion:

Reply by Ronnie Sharpe on November 12, 2012 at 3:48

I take 4-8 with meals :) I like push also. Could always try one pill per push.

▶ Reply ✉ Message ✎ Edit

This fits well with the discussions later... around the production of a prototype for the NIHR program grant.

The development of the enzyme dispenser continues with this back-and-forth discussion between me, Ronnie and Amber until late November, when the discussions for the enzyme dispenser peter out. The discussions happen elsewhere on the site- although Ronnie and Amber both have busy periods in their personal lives during these times (CF can mean long stays in Hospital sometimes for things like IV antibiotics).

Development post Blog call

After the meeting with Martin Wildman (13th December), and our email correspondence leading to the blog post in AIR (20th December) outlining the opportunity for out enzyme dispenser to be part of an NIHR Program Grant the development work on the dispenser was reignited.

This was kick started by Amber's comment after the blog post, which then spilled over into the enzyme dispenser thread on the Design Forum. Amber took the lead again:

Reply by Amber Richter on December 31, 2012 at 23:45

Hay guys, here's a brainstorming question for everyone =)

Because we always need our enzymes on us, I'd like to know more about what you already carry on you.

What do you Always carry on you? (if anything) examples are Keys, drivers license, money...

Where do you keep these? (on you)

Are you ever without them? if so, when?

Where are they when they at those moments you are not wearing them?

Also, where do you currently keep your enzymes?

▶ Reply ✉ Message ✎ Edit

Leading the discussions like this meant that the focus of the investigation was really 'owned' by Amber and Ronnie (since Ronnie is quick to reply to Amber's request for a brainstorm on the ideas).

Reply by Ronnie Sharpe on January 2, 2013 at 16:57

What do you Always carry on you? (if anything) examples are Keys, drivers license, money... The only two things I have on me almost at all times if I'm out and about are my wallet, car key and cell phone. Where do you keep these? (on you) In my pants/shorts pocket or sweatshirt pocket. Are you ever without them? if so, when? When I don't drive, when I'm not paying or when my phone is charging :) Where are they when they at those moments you are not wearing them? In a basket by my garage door or on my nightstand. Also, where do you currently keep your enzymes? In their bottle in my medicine cabinet in the kitchen. My wife usually has enzymes in a little change purse that we keep in her big purse or diaper bag. Otherwise, I just keep them in my pocket.

▶ Reply ✉ Message ✎ Edit

Reply by Ronnie Sharpe on January 2, 2013 at 16:57

I had my answer all neatly laid out and bolded, but it didn't translate when I entered it. Hope it still makes sense!

▶ Reply ✉ Message ✎ Edit

Reply by Amber Richter on January 2, 2013 at 19:16

It does! I laid out your answer in a drawing format. It looks silly, but it'll help when I'm sketching ideas. There was some very helpful information in this, thank you!

▶ Reply ✉ Message ✎ Edit

It was great to see these discussions happen naturally, without any sort of intervention by me. The information sharing has worked very well in the space- despite the limitations of the format with regards to the nesting of conversations.

Sarah Thornton, one of the CF dieticians here in Sheffield joined AIR to help add a bit of information about the scope and direction of the wider development effort:

Reply by Sarah Thornton on January 8, 2013 at 17:01

Hello! I am one of the dietitians working on the CF project.

The ideas you are having are fantastic and we can't wait to see the final product! Having a device that can track the amount of enzymes will be so useful.

One of the things that our patients do say is that when they are out and about they like to carry a holder in their trouser pocket (especially the boys) or handbag so may take a smaller holder out with them. But when at home they often have enzyme pots around the house (one in kitchen, another in bedroom etc). This probably doesn't help but just a thought in case it would work to offer different sizes that could all sync/download.

I work with another dietitian (Ailsa) and she is going to join the blog as well so feel free to ask us questions if you think we could help. We will add our ideas to the pot if we have any!

thanks, Sarah

▶ Reply ✉ Message ✎ Edit

This served as a good introduction to some of the wider team here in Sheffield. Amber posted a welcoming note as a reply.

The time for the development of the prototype was dictated by the external pressures of bidding for the £10,000 from Abbott pharmaceutical, and also the pressures of including the enzyme dispenser as part of the wider NIHR program grant. Martin wanted a prototype inside of a month, so the development process happened quickly. This was facilitated by the open and distributed nature of the process – we didn't have to wait for workshops at specific times to move the development forward. It all happened when people could chip in – the cognitive and temporal 'overhead' was less than a traditional series of Future Workshops, or Participatory Design session (involving design games, etc).

By Mid January, we were discussing different products that we were inspired by, and also delving into the specifics of different containers. Sweets were a good topic, since some packaging is very intuitive and complex – whilst also being international (which is a consideration when collaborating in an Open Design project).

Tic Tac, Pez and Smint were all discussed, although Amber took it upon herself to test the Tic Tac idea herself:

Reply by Amber Richter on January 14, 2013 at 18:52

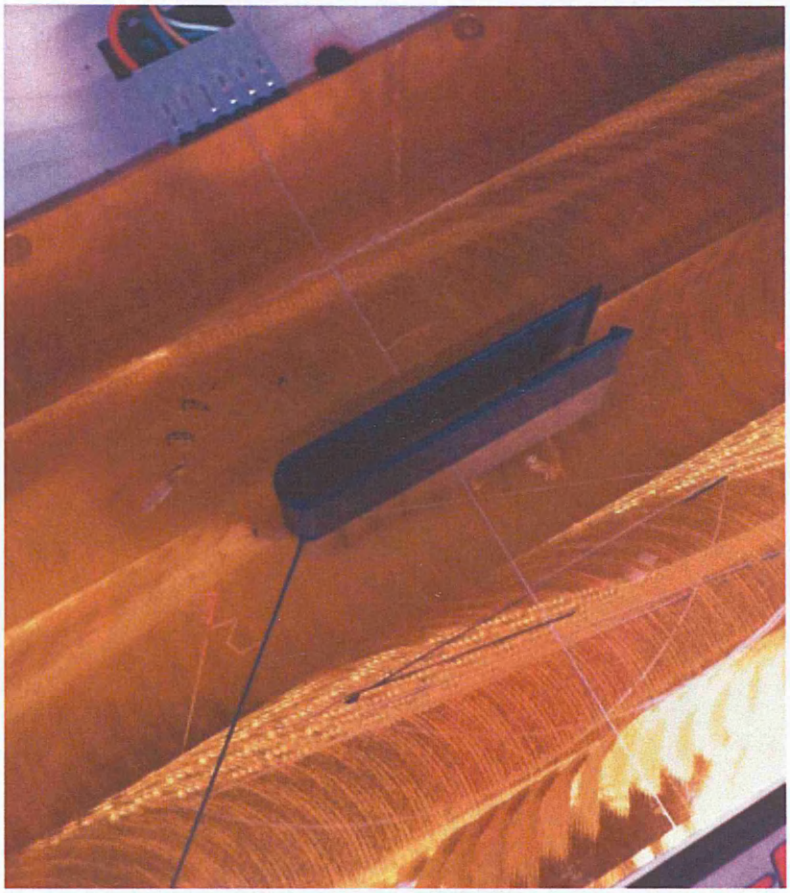
Matt I'm going to revert back to your tick tack idea and give that a try. I think there could be a benefit to it if you only get one enzyme out at a time. Because it would be easier to fill but still doing single dispenses. This might help us with the prototype, which will have to count one enzyme at a time. I'll keep this updated on how its working.

How did the meeting go? I know we are on a more condensed schedule to work on this. Would it be helpful if I facebook the discussion to other cfers I know? that may help get more than just a few ideas and opinions on here.

▶ Reply ✉ Message ✎ Edit

Amber takes up a discussion we had earlier and uses it as the basis for her own experiments and discussion. Also, Amber engages others in conversation outside AIR, acting as recruiter and evangelizer for the project.

For example, I've just printed this idea... it's a clip (like a hair clip) that will old the Creon, and when it's pushed down, then the clip will splay and the Creon drop out. Hopefully one at a time... I'll let you know when I've tested it!



I've also attached the Rhino 3D CAD file, so anyone can have a look at that if they're interested.

Attachments:

Mechanism 1.3dm, 160 KB ✖ Delete

The above photo shows a post that I put into the discussion to show another prototype based on a sweet dispenser (Smint) and a hair clip... Amber and I discussed the prototype, and how it might work. I shared the Rhino CAD file in the space, and Amber (in particular) was keen to have access to this data.

Amber trialed the Tic Tac box, and posted her results:

Reply by Amber Richter on January 15, 2013 at 4:03

Tick Tack trial -

Ok key learning:

The opening is too big/ the enzymes are not guided enough to come out one by one. You have to hold it in a very slightly slanted position to get just one to come out. Most often it despondence 2.

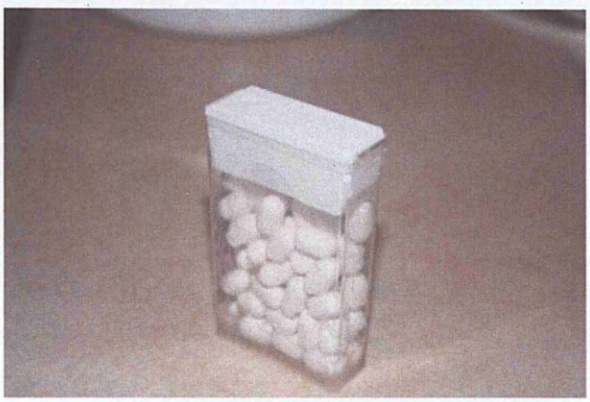
Very easy to fill, simple to use.

has the benefit that you Only touch the dose you are taking immediately, so you do not contaminate the other enzymes with bacteria from your hands.

http://www.youtube.com/watch?v=8jBL-DyZIDs&feature=youtu.be

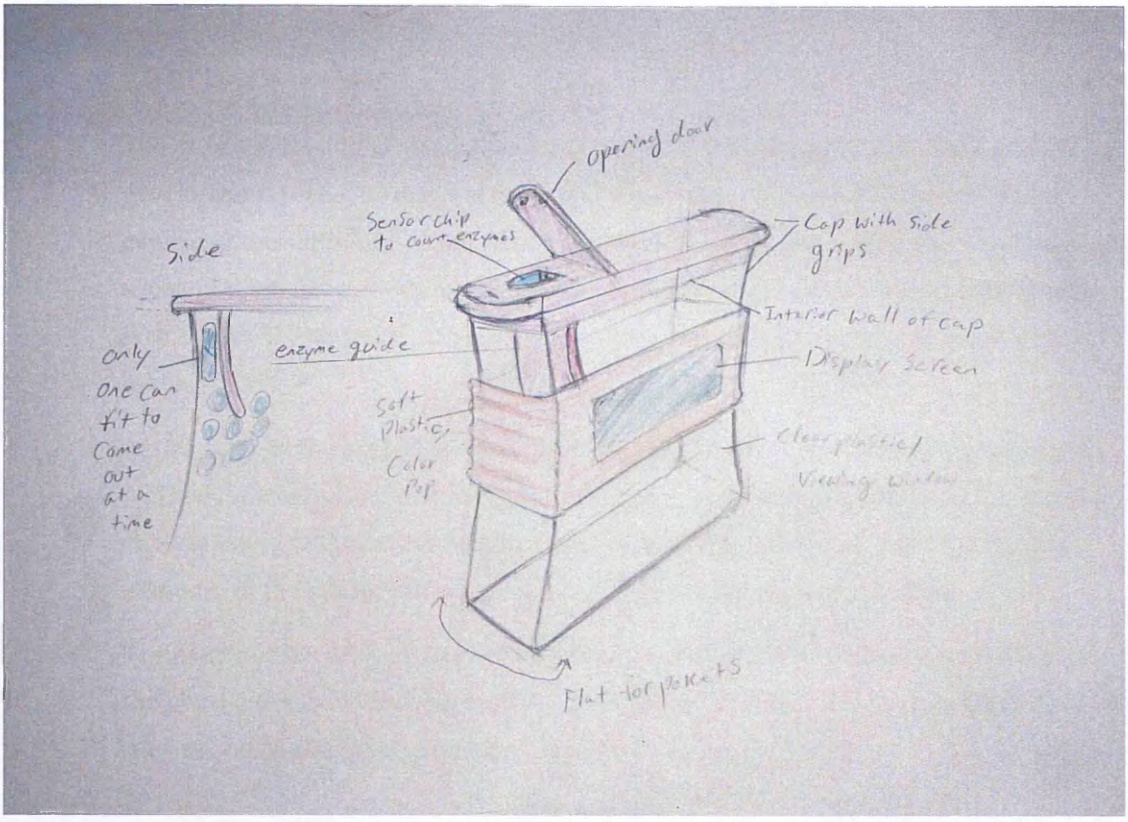
That is the video of the trial.

Not water proof, but considerably water resistant. (a few tick tacks were harmed in the process of that discovery)



▶ Reply ✉ Message ✎ Edit

The issues highlighted by Amber here show the development process, and learning from making. The development of this prototype petered out, but the considerations made about the other aspects of the design influenced the development of the later prototypes. For instance, the sketch work that Amber added talked about future aspects of the dispenser – and also highlighted the optimum orientation for the overall form (something flat, and rectangular making the best use of the space). Shown over.



The issues with the prototype showed that while it was easy to fill, the enzymes were difficult to dispense in a singular fashion (Ronnie's comment from before highlighted the specification for a single enzyme per push).

In conversation with Amber, the 'clip' idea was fleshed out more. The problems of the prototype being too exposed to the elements, and also the difficulty in dispensing the enzymes reliably were highlighted as not being very good points.

Similarly, the development was being informed by the fact that the prototype would eventually be 'chipped' with a data logger, and that we should be mindful of that. The requirement that the people using the device would benefit from inclusion of wireless technologies like Bluetooth was noted- and although this is beyond the scope of the project so far, when talking with Ben it's not beyond the realm of possibility.

February – April 2013

The month following the busy Christmas and New Year period in AIR continued the development pace. The enzyme dispenser was becoming more 'fleshed out' in the conversations with Amber and Ronnie – although Amber was taking more and more of a lead in these discussions. It's worth noting though that Amber makes an effort to be inclusive in her language – appealing to others with offers of help, or to involve others in the process.

At this stage in the project, we had until the end of February to provide something that worked for trialing and demonstration purposes. In my role as producer / facilitator, I experimented with some different plastic to make the prototypes with. This was in response to the call for different colours / finishes that we had discussed.

The need for this device to be entirely able to be 3D printed was also required – since the plans were to be disseminated via the internet for others to see / use. Shown below is a post highlighting the development so far.

Reply by Matt Dexter on February 12, 2013 at 0:48

Just to show you some of the prototypes so far... All with varying degrees of success! I'm going to bed. More tomorrow!

▶ Reply ✎ Edit

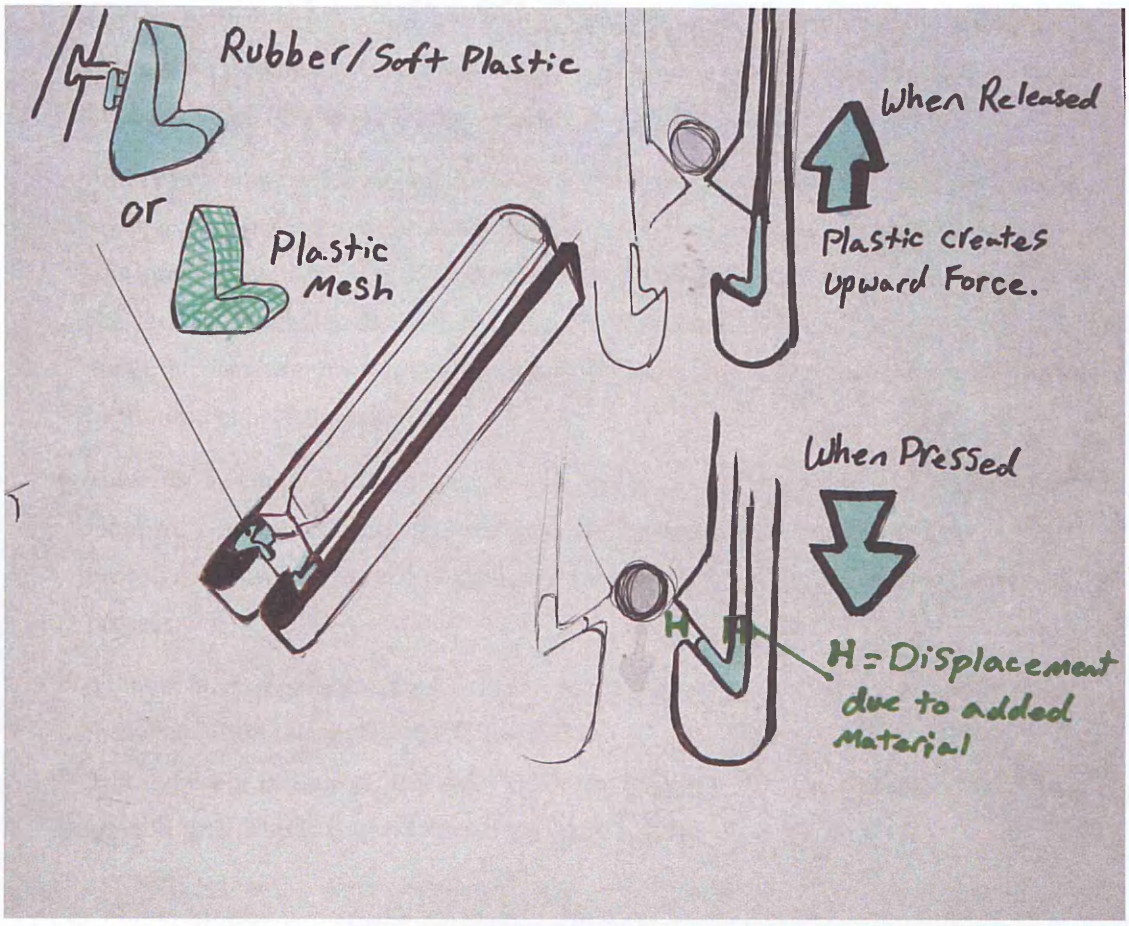
Reply by Amber Richter on February 12, 2013 at 15:30

This cleared up all my questions! I see how you can cover it now. and my mind is spinning full of stylizing ideas as well as a few on how to cleverly cap the opening that the enzymes come out of, and ideas for filling it. Now I just need some time to sketch! I'll hop back on here once I finish what I need to do for school =)

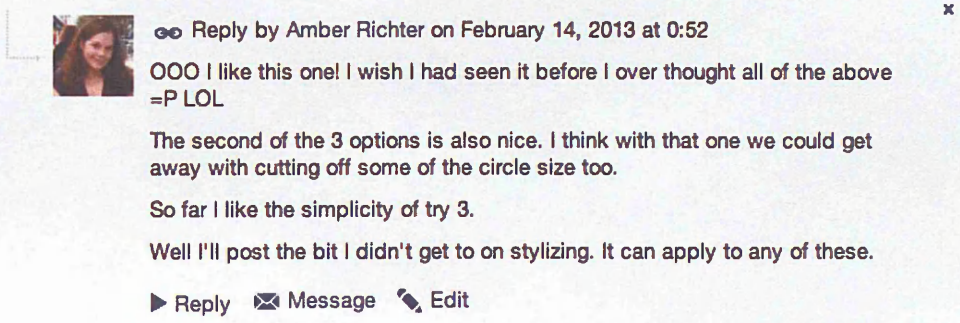
I can see how the plastic tolerance could be a dozy, but overall this is looking great. The testing phases of models has a way of taking a while (speaking of witch that is the homework I am getting back to soon).

The post was intended to show the development effort in making some mechanical components for use in the dispenser- the spring to make the device recoil & reload, and the experiments in making the 'clip' longer to try and increase the capacity of the prototype. We also tried different way of getting the 'clip' to pinch enzymes above the one to be dispensed by simply having different geometry on the walls of the prototype- all informed by the gravity-fed sweet dispensers.

Amber took the ideas for the clip dispenser and ran with them – mixing in inexpensive materials that performed mechanical functions – silicone, plastic mesh – and while these did not play a part in this development, they absolutely informed a *key* aspect of the dispenser towards the end of the month. Shown below is an example of her sketch work:



The design direction moved, since quite by accident I had a thought about how to stop other enzymes from dropping as one is dispensed. However, this highlights a major failing of the site – as I was developing this idea, Amber was developing the sketch work above. Consequently, as I posted the initial idea about using a 'rotating drum', Amber noted that she wished she had seen this before!



This highlights the need to post ideas more quickly – to publish *soon*. Raymond talks about this in *The Cathedral and the Bazaar* (2001) with Linux development happening across so many different actors, the best way to avoid the duplication of effort is to see what is happening as soon as possible.

It might be that with the tools I have, that this delay is inevitable – and it is certainly better than the gap between traditional PD workshops. Still, this is a finding that should not be ignored. I'll need to try and mitigate it.

Amber immediately follows up the video of the drum prototype with a long post about styling, and the need to think about the number of enzymes needed for a day. Adding this information to the info discussed in Sheffield (with the CF team), this means that the device either holds them all, or is easy to fill. Ronnie's comment from last month about the dispenser not necessarily needing to carry them all in one go is something to be mindful of here though.

Towards the end of February, Amber and I had discussed a lot of ideas, and also done a lot of work in the background to facilitate the design and development of the prototypes. Towards the end of February, we were nearing the end of the development process.

It would be disingenuous of me to assert that the development work was solely that of the collaborators living with CF- there is a lot of me in the development of this prototype. For instance, the wavy 'throat' that holds the enzymes in place without them jamming the drum was something that I came up with (shown below):

However – I consider this prototype to be a wholly collaborative affair. There is no way that I would have known the most subtle of the facets that make something appropriate for someone living with CF would entail. This is true of the enzyme

dispenser's continuing development, but also for products that I had no clue needed to exist – like the Treatment Cabinet.

Amber takes the prototype, and suggests aesthetic considerations that match or compliment some of the physical aspects of the prototype. This reflection on the aesthetic is a recurring theme for the discussions, and Amber has a keen sense that this should be a key aspect of the dispenser.

Reply by Amber Richter on March 1, 2013 at 0:10

=D Very cool! I'm excited about this one. I think marrying together the function and form of that wave to keep the enzymes oriented the right way will also create a really cool look if we use translucent material. In that case, also allowing for a window. A great example of this is something us CFers know well is the Acapella.

However it is cool to see the inside of this thing work, it is not actually necessary to its function. For us, seeing how full the pill case is, is also a necessity. But just because it's necessary doesn't mean it can't also look cool.

Big Pharma Conference Call

On March the 6th, I attended a conference call at the Sheffield CF centre with representatives of Abbott Pharmaceutical, and representatives from the unit (The consultant (Martin Wildman), a dietician (Sarah Thornton) and a specialist nurse (Ailsa Milne)). The topic of conversation was the development of the enzyme dispenser – specifically being developed to take the Creon brand of enzymes, as they are amongst the most used (they account for over 90% of the enzymes prescribed in the UK, for example).

The conference call was a good opportunity to present the ideas behind AIR, and also to gauge some feedback from a big Pharma company. The main focus of the call was for Martin and his colleagues from the unit to profile the work of the NIHR program grant, although the information I had provided formed part of this.

I prepared some slides to cover the development effort thus far, with some background on the theory (Open Design enabling people to participate that can't), and also a sample business model based on an 'open parts' strategy.

The call was very informative, and also well received. However, there were 3 representatives from Abbott pharmaceutical on the call- the UK head of Creon, the European Head, and the global head for Creon. As the idea passed up the 'ranks', the reception to the development process became more muted. The UK head really enjoyed the idea, even musing that this could be a strategy adopted by Abbott for their own strategy around Creon. They even went as far as to suggest that Abbott could host competitions and the development work for similar enzyme dispensers on their own company servers. This represented quite a forward-thinking leap, since there was a recognition that the enzyme dispenser represented a 'beyond the pill' strategy for Abbott as a Pharma company. Similarly, that this development work is not a distraction for Abbott, but that they would stand to gain in fostering a niche network around their brand of enzyme.

However, the European head was more cautious – citing regulatory concerns and the issues around strict legislation for 'marketing' or advertising pharmaceuticals. The global head was even more muted in their response. Overall Abbott seemed happy that there was a prototype, but overall they weren't at all bothered about fostering the activity that might provide more prototypes- or the fact that the prototype would not have existed without the deep participation of people with lived experience of CF.

From discussions with Martin, it appears that the small amount of money being bid for from Abbott will almost certainly not materialise. The details are confidential, but Martin, and the enterprise centre here in Sheffield have strongly suggested that a creative commons license (ideally non-commercial) be applied (or more accurately, prominently displayed) in AIR. The enterprise centre advised that a third party wouldn't be able to preemptively patent any ideas in AIR (or, rip them off) because they constitute 'prior art', and since they are published in the public domain, a strong case could be bought to counter any spurious claim of ownership by a third party.

On reflection, the conference call to Abbott has highlighted the reticence that seems to pervade the discussions about open source. Especially in an industry that is traditionally risk-averse, and used to adherence to strict regulation around issues of development, licensing and sale for their products. However, the idea behind AIR (and this PhD) wasn't entirely lost on the company – at the very least, the UK head understood the implications and the opportunities that might be there.

A working prototype

By this time, we had successfully developed a prototype that would dispense a single enzyme per push. The posting of videos (uploaded to YouTube and then embedded in AIR) communicated the success of the development process.

Reply by Ronnie Sharpe on March 1, 2013 at 15:30

That looks great!! Awesome work guys :)

▶ Reply ✉ Message ✎ Edit

Ronnie had taken more of a back seat with the later stages of the development for this enzyme dispenser. He had contributed to the discussions, but not to the extent of the Treatment Cabinet- however, with a young family it could be that the rapid pace of development for the dispenser had meant that Ronnie was not as able to be part of the discussions as Amber and myself. Amber is a student, as am I – Ronnie runs his own business, so as per the Francis & Reyes (2012) paper the natural pace of Ronnie's development is slower than ours. In fact, by the end of April the development pace slowed again as individual time commitments meant that the participants had other focuses. For instance, Amber had a wedding to plan, and Ronnie had business to attend to.

April – July 2013

The section here covers a long period of time, but also a significant amount of activity, mostly out of AIR. During the period of April – June 2 conferences were attended, as well as a Design Bootcamp in Amsterdam. These three events allowed for more reflection and consideration about Open Design and its implications for the work of this PhD.

In the first week of April, the enzyme dispensers were printed and shipped out to the participants for evaluation. Six enzyme dispensers were shipped in total, with feedback coming in from 4 participants. This feedback was received over the course of late May, late June and July. This feedback is covered towards the end of this section.

10th European Academy of Design Conference

The first conference came in April, with EAD 10. The previous EAD conference in Porto (EAD 09, 2011) ended with an agreement at the plenary session that more 'making' would be good for the future EAD conferences, and as such EAD 11 in Gothenburg had a significant track titled 'MAKING TOGETHER - Open, Connected, Collaborative'.

This PhD case study was a natural fit for the track, and a paper was accepted to the conference. This paper is referenced in the thesis for the PhD, and included in the Appendices.

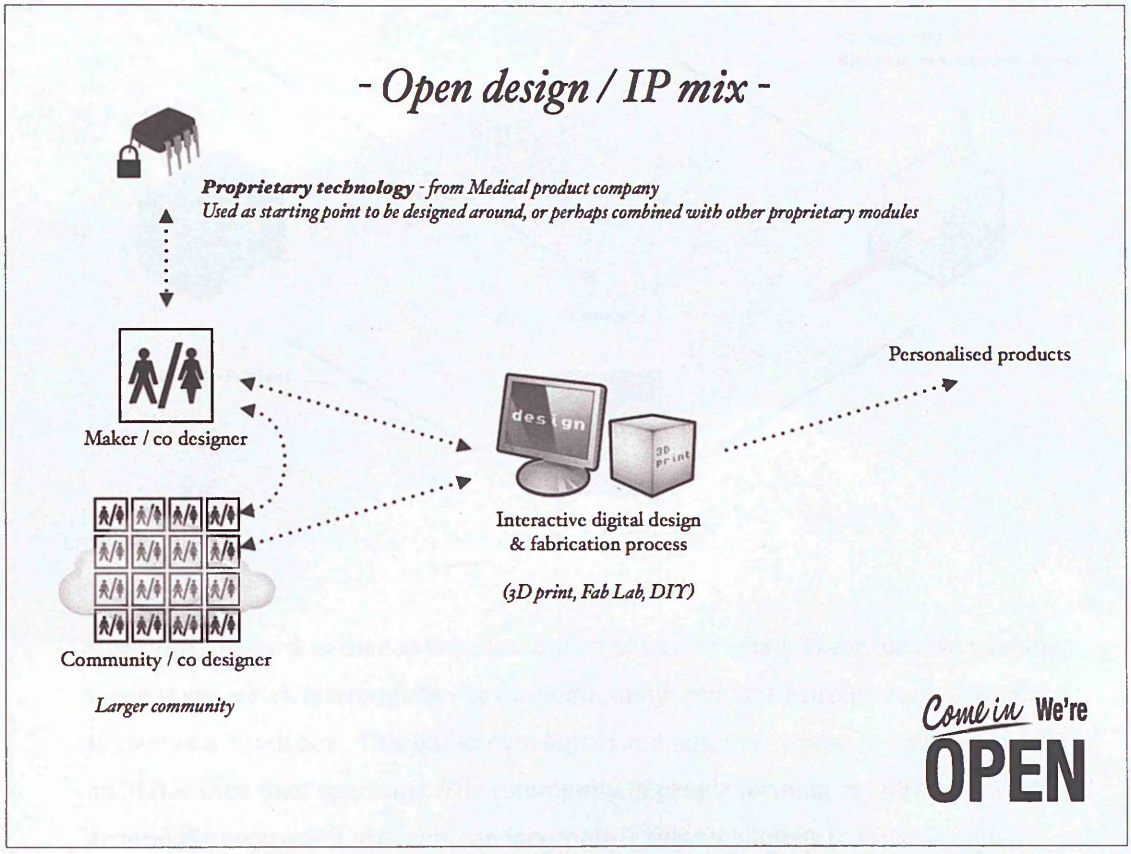
The paper for the conference outlined the work competed so far, and the reasons behind the use of Open Design in medical product development (specifically, in the collaborative creation of prototypes).

The research was also used as an example in another paper for the conference, by Paul Atkinson and Leon Cruickshank, entitled 'Closing in on Open Design: comparing casual and critical design challenges'. The reference for this paper:

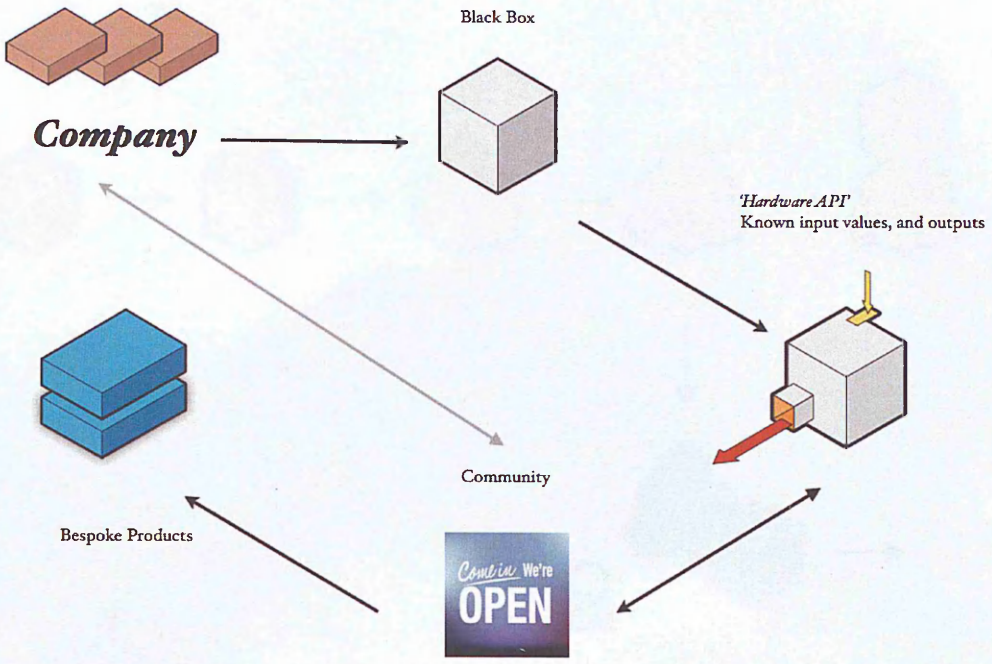
> Cruickshank, L. & Atkinson, P., 2013. Closing in on Open Design: comparing casual and critical design challenges. In Crafting the Future: 10th European Academy of Design Conference. Gothenburg, pp. 1–15. Available at: http://www.trippus.se/eventus/userfiles/39743.pdf.

In their paper, Atkinson and Cruickshank take a critical look at the opportunities and potential pitfalls for Open Design. In particular, the tendency for Open Design to be discussed in rather utopian terms- also that design is assumed to be the only method for new product development. My research is used as an example of a pragmatic approach to using Open Design, in that the *benefit* of the users not having to meet physically to be part of the design process *enables* participation.

The paper I delivered at EAD was a summary of the research so far – of the development work that has led to a functioning prototype, but also expanding on the ideas behind the research, for instance, the ideas for business models, and how these have evolved. Shown below is the first of the business models, and how this might work in an Open Design context.



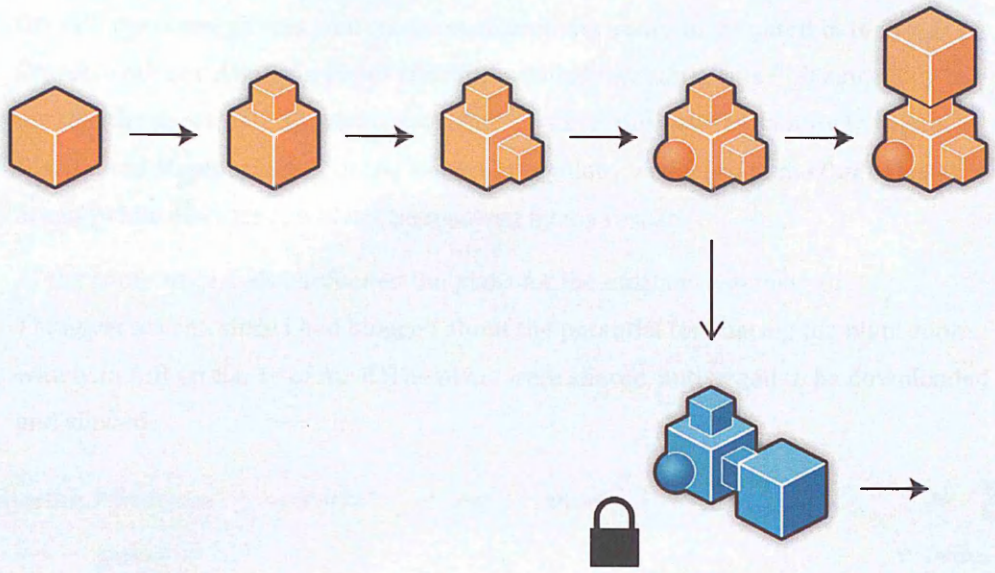
This is a slide from the presentation to Abbott from the conference call in March. The slide's graphic is an adaptation from an overview of the Open Design process from Atkinson's chapter in *Open Design Now* (2011). The use of proprietary technology could be used in an open source design process. This is expanded on below:



Here, the company in the top left develops products for retail. These have an enabling technology, which is irreducible by the community- this is the proprietary technology known as a 'black box'. This has known inputs and outputs, similar to a software API- an 'if this then that' operation. The community of people forming the niche network around the company's products can incorporate this technology in their designs, meaning custom products for themselves. The company, assuming that they deal fairly, and ethically with their community then has a source of new product development, customisation and also product support and evangelists. This is an 'open parts' strategy for the company – they retain the rights for their components, but not necessarily for the rest.

Of course, this would not necessarily stop the company building products based on the open source designs from the community- but this *would* be conditional of the company engendering the community and dealing fairly with them (collectively, or as individual actors).

Finally, the idea of a 'fork' of open source development might be possible – shown below:



Here, the open source development is shown in orange. The artefact develops as per the work of the community, and at some point the company who cultivates the community (say, as the open source development happens in a niche network around a product, product line, or entire catalogue) may decide to fork a version of the open source development. This would have to be done ethically and under discussion of the community (or the entities responsible for the idea and derivations) to continue to ensure support for the whole community's continuing evolvement with the company.

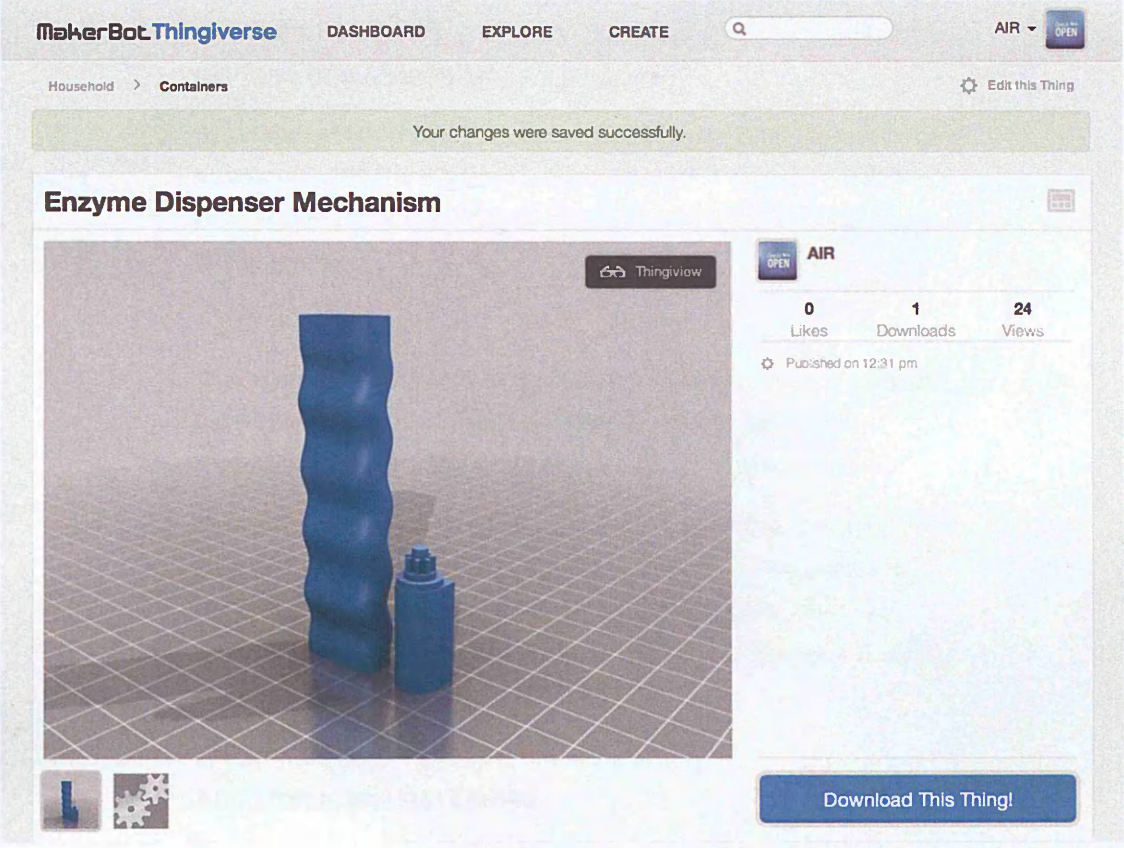
This way, the company would not interfere with the open source development, and the community would continue to enjoy full and unfettered access to the open source development that could continue. Similarly, the company can develop and retain an option on the technology that is developed from this fork. However, in order to continue to 'feed' the development of the open source stream, or as part of the licensing deal struck between the content creators and the company, this 'closed', proprietary development could be released into the open source stream after the costs have been recouped, or after a specific length of time.

Of course, a company might simply decide that they will produce the hardware 'unprotected'- that is to say, that if the company has ready access to manufacturing equipment and a known market, they might choose to produce the product and be first to market. This strategy relies on the fact that not every consumer has the time, talent or inclination to design and produce their own artefacts. This conference was the first

opportunity I have had to discuss these business models, and the impact that they might have. For instance, the idea of building a business solely based on being 'first to market' was new.

Overall, the research was well received, though the issues highlighted in the Cruickshank and Atkinson paper remain, and likely will after this PhD since they fall outside the scope of this investigation. For instance, the issue of liability in Digital Distributed Manufacturing, or the impact of regulatory concern in the Open Design arena (while discussed) will not be resolved by my research.

At the conference, I also uploaded the plans for the enzyme dispenser to Thingiverse.com, since I had blogged about the potential for sharing the plans more widely in AIR on the 1st of April. The plans were shared, and began to be downloaded and viewed:



The dispenser was uploaded a day before the presentation at the conference, and it had received 25 views in a matter of hours (at the time of publication of this thesis, the dispenser has been downloaded 276 times, and viewed 1486 times).

The dispenser was given the following description, taking into account the licensing advice from before, the aim to credit the collective input from AIR (and not 'take the glory' as the researcher) and also the use of a disclaimer (as used by those in the Open Source software community):

> This prototype has been collaboratively produced with people who have Cystic Fibrosis - the mechanism shown here reliably dispenses a single enzyme capsule per push. More information at **http://airdesignspace.ning.com**
>
> *Important - Please Read*
>
> This is a Class I, customised medical device (as defined by EU Directive 93/42/EEC | **see here (PDF)**) this should be used under advisement from your clinician. It is provided here with no guarantee, in line with Free/Libre Open Source Software.

Recognising that the instructions for disseminating the plans for Open Source hardware are important, here are the instructions that accompany the listing on Thingiverse.com:

> This dispenser has been collaboratively developed with people who live with Cysitc Fibrosis. The process has been happening in the 'open', at the web space **http://airdesignspace.ning.com**
>
> As such, we would really like it if you print this, and have some comments on how the mechanism might be improved (or if you make a derivative) that you post a link at the above webspace to the thing you create & upload to Thingiverse.
>
> ~~~~~
>
> The dispenser itself is quite simple, and this file will work with a popular Enzyme brand (we can't name the make, or manufacturer), with approximate capsule dimensions of 19mm length x 6mm diameter.
>
> There are 2 files above - Enzyme_Transparent and Enzyme_Opaque. Print both; and as the name suggests, the transparent file is best printed in a clear plastic (so you can see the number of remaining Enzymes, and whether there is one ready to dispense). The opaque file can be printed in any colour you desire.
>
> The parts are assembled as per this Youtube video:
> **http://youtu.be/iGJAYZvG-Mw**
>
> The written instructions are complex, and it's much easier to watch the video to see assembly. The elastic band you'll require is a #32 (type 32) elastic band. If this is called something different in other parts of the world, I can post the dimensions.
>
> Tolerances may vary, depending on the plastic used for printing, and the print settings / environmental conditions. For information, approximately 25 of these have been printed reliably on the following machine and settings:

MakerBot Replicator (Dual) V 7.0 firmware ReplicatorG (0040) 25% infill, 3x shells

PLA 230ÃÂºC Extruder 50ÃÂºC Bed, covered in 3M Blue Tape (sticks like poop to a blanket that way).

Finally, this is a WIP. The development of this continues, and it should be noted that there are still issues to solve! Not least, how this is filled reliably and speedily- and what sort of casing this mechanism might fit into. Perhaps a CNC wooden or Aluminium case, made in a Fab Lab? The sky is the limit.

Pharmacovigilance

In order to comply with the regulations set out in the EU directive governing Pharmaceutical development and provision, aftermarket vigilance is required to ensure that a pharmaceutical product is performing as intended.

In order to best spot this researchers working with a pharmaceutical product, or coming into contact with a product (indirectly) have to be trained to recognise information that might be given by a participant that is significant to the Pharmaceutical company. For instance, if a participant discusses in a study that their pill X is not working as expected / intended, then the researcher should report this feedback to the Pharmaceutical company.

As such, Pharmacovigilance training was organised between Martin Wildman and the other members of the Cystic Fibrosis ward involved in research (as well as myself, and Ben Heller from Sheffield Hallam University) on the 18th April 2013.

As part of this training, the research in AIR was profiled to the Abbott Pharmaceutical employee who was delivering the training. The niche network that had formed around the Creon enzyme (that Abbott hold the license for) was obviously using the Creon brand name to describe the developments. However, there is strict legislation governing the advertisement of pharmaceuticals, and after discussing the research with the representative from Abbott I was asked to cease using the Creon brand, as it could be construed as advertising.

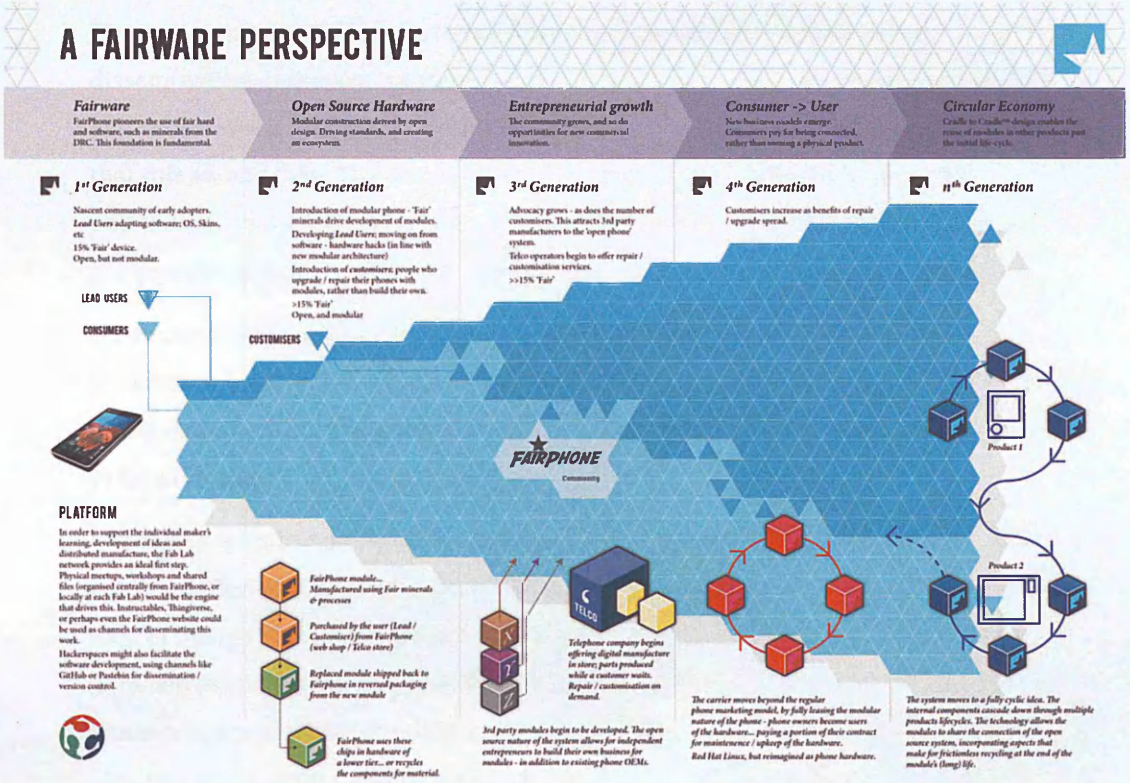
Participants could use the brand name, but unfortunately I was unable to. This meant taking down the videos that showed the Creon dispenser prototypes in action, as the Creon capsule was clearly visible. Since these discussions had already happened in AIR, this did not dampen the development process- but it has harmed the overall community space.

This raises an interesting question, can a niche network exist when the researcher is not necessarily allowed to discuss the brand name of the product being developed?

Fairphone Design Bootcamp

On the 30th May to the 1st June Fairphone held a Design Bootcamp[4] to discuss the different facets of their 'Smart Design' philosophy. This included presentations and discussions about Conflict Mineral sourcing, Cradle to Cradle Design, and Open Design. I was invited to speak about Open Design, after contacting the Waag society about the possibility of simply attending.

This was a great oporutnity to discuss the learning so far from the Open Design work conducted for AIR, and also see how Open Design could be incorporated in a different sphere of product development- that of smartphones. During the weekend, I worked with Casper Jorna (Handset Sustainability Manager at Vodafone) to come up with a roadmap detailing the development of future generations of the Fairphone. This is detailed below (Also in Annex X):



Developing this roadmap with Casper as part of the bootcamp meant bringing in ideas from across the assembled team (at the bootcamp) as well as amalgamating the 'open parts' strategy as mentioned before. This also meant visualising the mix of consumers, Lead Users and 'Customisers' that would form the Fairphone community.

International Symposium of End User Development (IS EUD '13)

I attended the 'Cultures of Participation in the Digital Age: Empowering End Users to Improve Their Quality of Life' workshop at IS EUD '13 at the IT University of Copenhagen on the 10th June 2013. This workshop was perfect to deliver a

[4] http://www.fairphone.com/2013/06/12/design-bootcamp-results/

presentation about AIR, and also see more of the landscape of other projects from around the world. The discussion centred around the nature of participation, and how often the *term* participation is used in the loosest sense- that is, for an activity that could be considered tokenism (of some degree). Sherry Arnstein (1969) discusses such approaches in her *Ladder of Citizen Participation*- people can be involved in a project only to have a say which is then disregarded by the organisers of the activity.

In this sense, I've had to focus on what type of participation has happened in AIR – has the work been tokenism?

I would say that the work has been participatory- the participants and I have collaborated on generating ideas which have been developed in a space where they could be directed by the same people who have originated the ideas. This 'genuine participation' is not tokenism.

The conferences that I presented at during this period have helped in the dissemination of the work conducted in AIR, but also in understanding the reading behind the work- helping to try and form some ideas for further work and the direction that this should take. The use of Open Design to foster collaboration amongst populations that are barred from a Participatory Design methodology is shown here in the creation of these prototypes (from this research) to be a viable endeavour.

However, it is clear from the work presented at EAD (both my own, and the Cruickshank and Atkinson paper) that more research is needed to consider the impact of regulation, standardisation and even facilitation [of the collaborative design activity] in Open Design.

The final keynote from Pelle Ehn was exceptionally useful- in it, Ehn discussed the notion of 'Design Thinging', where a Thing is a socio-material construct. In taking the idea of Design Thinging (rather than Deisgn 'Thinking') a bridge could be made between Participatory design and Open Design – since in Open Design the aim is to create a space in which the design activity continues ad infinitum. This would be a good idea to expand upon for my thesis, to try and reconcile the ideas of Participatory design, Action Research and also Open Design.

24Hr Inclusive Design Challenge | Design 4 Health Conference

From the original plan for the PhD back in the first year (September 2011) the decision to compare a Participatory design methodology with an Open Design methodology was considered[5], but abandoned after the RF2 (commencement from MPhil to PhD. End of

[5] This was abandoned when it was realized that without empirical data to compare outputs from the two concurrent studies, the results would be of questionable value. More fundamentally however, was the lack of resources available in the PhD to employ a separate designer to facilitate one of the projects. This would have meant that I would have had difficulty in demonstrating that the two projects were not 'cross-pollinated' by the researcher bleeding ideas across.

year 1). Part of this plan was that a 'traditional' User-centred methodology would be contrasted against an open-source collaborative design project.

The Inclusive Design challenge was to be the vehicle by which to draw the comparison. This ultimately did not constitute the main focus of the PhD (it will not be included as a significant part of the Thesis), as at the RF2 stage the decision was made to focus on a single, longer Open Design study (Hence AIR). However, due to an existing relationship with Julia Cassim (Visiting Senior Research Fellow at the Helen Hamlyn Centre for Design at the Royal College of Art, UK) who developed the 24hr Inclusive Design Challenge over the last 10 years, and the opportunity to run the challenge as part of an international design conference I undertook the organisation and execution of this activity.

Planning, organising and running the event took a significant amount of time, but towards the end I had a great deal of help from other members of the User-centred Healthcare Design team. Running the event allowed for the engagement of much of the local CF teams for both the adult and the children's services. This was a good opportunity for networking, and the ability to showcase the PhD research to a wide and varied audience.

Enzyme Dispenser Feedback

April, May and June were busy months in disseminating the research conducted in AIR via peer-reviewed conferences, as well as receiving feedback on the performance of the first crop of enzyme dispensers.

The planning, organisation, and running of the 24hr Design challenge also had a detrimental effect on the winding down of AIR, as the work required to ensure the success of the event intensified over the curse of June and into the beginning of July.

As such, the work to produce individually customised dispensers for each of the participants (after their feedback) was not completed. The limits of the case study are evident here- in approximating the Open Design process by not giving each participant a 3D printer themselves (due to the PhD resources not allowing for this), or access to community making spaces (Fab Labs, Hackerspaces, etc) then the participants were reliant on me alone for their prototyping requirements. If the participants had access to their own equipment, then they would have been empowered to produce artefacts for themselves- the project would have been more emancipatory.

However, some good feedback was provided. The feedback itself seemed to centre on the aesthetics and ergonomics of the prototype- since the device itself has sharp corners, and also some small gaps (particularly around the barrel, shown below).

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> - Filling it is time consuming and a bit of a pain. I don't like having to touch each medication to fill it.
>
> -It is not the most ergonomic yet.
>
> Now for the good =D
>
> + It is very easy to dispense the enzyme
>
> + Makes tracking enzyme intake very easy by dispensing 1 at a time.
>
> + Great size for pocket storage
>
> +Also big enough to find in my purse and fit into pockets.
>
> + Fun to use, this may be a positive for children who see taking there enzymes as not fun.
>
> + I felt less socially awkward using it. Let me explain, its hard to tell what it is, and it speeds up the process of getting your enzymes out. So, in a social setting I'm not jumbling around a pill case and pulling 2 pills out of a container filled with pills.
>
> + you only touch the ones your taking, this is great because your not contaminating the remainder of the pills being stored.
>
> Ronnie - do you have a way to measure your Zenpep?

The final line refers to the brand of enzyme that Ronnie uses (obviously different from the brand we as a whole were designing for). Here again we see a tension come from this research that would be mitigated by the participants having their own access to Distributed Digital Manufacturing... the pressures for the entity hosting or initiating the design activity (me, similar to the corporate entity in the business models above) have potentially different pressures to the participants. As such, a more emancipatory method is a 'true' Open Design method, that would allow for the participants to 'design after design'. This moves to the 'Design Thinging' talked about by Pelle Ehn in his Keynote address from IS EUD '13 – the infrastructuring of design projects to allow for design after design.

Feedback and correspondence from Thingiverse.com

AIR was not the only source of feedback from this project. With posting the files to Thingiverse.com other makers on the site contacted me in connection to the listing. For instance, I received the following piece of email via Thingiverse (7th June 2013):

> Hi,
>
> First off, I just want to let you know that personally, I think what you are doing with the enzyme dispenser is great and is probably a great potential service to CF patients that have trouble with their enzyme dispensers. So please don't consider this message to be in any way disparaging of what

> you are trying to do. I just feel the need to give you a heads up on some things in case you are unaware.
>
> In my day job, I'm a regulatory quality assurance manager at a medical device company. So, I spend a lot of time working with US FDA and other countries medical device regulations. Under many countries' regulations, your enzyme dispenser is considered to be a medical device. The open source project designing it would be considered a spec developer. And the testing you are doing where people are making the device and giving you feedback would be considered a clinical trial. Assuming you're doing it in the US, all of this has the potential to get you into some trouble if anyone from the FDA finds out about the project. If you're not familiar with medical device regs, I'm sure this may seem stupid to you.
>
> I'm guessing that unless anybody gets hurt and reports it, the worst possible consequence you would face would be a nasty letter from the FDA followed by more severe actions if the project continues without following the regs.
>
> If you haven't already done so, you should probably hunt down a regulatory consultant to give you some guidance on what you should do to avoid getting yourself into trouble. You may even be able to find one that would be willing to provide a free service in line with the open source nature of what you are doing.
>
> Good luck with a successful project!

As is usually the case when talking with other members of the maker community, the tone is very civil, and it's good to hear that someone working in the regulatory industry likes the work that is being done here. Printed_Solid (the user who sent this message – Thingiverse allows anonymous posting) advises that regulatory advice is taken before proceeding further. After discussing some of these ideas further with Printed_Solid, I receive a reply with some more interesting topics to consider:

> Hi Matt,
>
> Glad to hear that you have everything lined up with MHRA. I'd be up for a skype chat sometime, but just for bouncing ideas around or for anonymous feedback. I wouldn't feel comfortable putting my name behind anything. My employer has made it clear that they're OK with me doing a 3D printing and design business on the side as long as I keep it separate from anything that could potentially be perceived as conflicting with my day job.
>
> I think your concept is great and truly fascinating from a regulatory perspective. Seriously, for me as a QA, the concept of open design for medical devices is as interesting as the 3D printed gun thing.
>
> There are three topics that pop into my head around your project.

> First is that I think it aligns closely with one of the things that regulatory bodies are really starting to push on, which is usability / human factors (supposedly the two words have different connotations in the US vs Europe). Device companies have historically focused on designing around user needs as the companies define them in design inputs. They will do marketing studies and perhaps clinical trials, but they're typically late in the design process and structured around a rigid set of acceptance criteria. There is not a lot of flexibility to really adjust to user preferences as long as the design satisfies the design inputs. Newer expectations are that the user is involved early and often to identify potential use errors. Use errors being situations where the design functions as intended, but the user does not use the device correctly either due to non-intuitive design, poor training, physical disability, etc. If you're not familiar with it already, you might want to search for FDA Draft Human Factors Guidance 2011 and read BS EN 62366. AAMI holds a great course with some experts that might provide you with some great input around this topic.
>
> Second is that you're potentially setting some liability issues on their ear. If there is not a big fat medical device company to sue, do the number of lawsuits reduce? IMO, the litigation side of things is a primary reason why healthcare costs in the US are so high.
>
> Third is kind of a downer, but still interesting. Primarily our government agencies are theoretically watching out for the public health and use the tools of quality systems to help them monitor companies design and manufacturing practices. Traditional quality system regs / standards all include a pretty substantial bit about management responsibility. The purpose of that is that someone(s) is accountable for when things go wrong. We call it the go to jail list. Given that they are accountable for when things go wrong, they take a more active involvement (or appoint people) in making sure that things are done above board and not shortcutted. Running an open project like this basically means that there is no management responsibility. What happens when inevitably something goes wrong and someone gets hurt? Probably not relevant to the enzyme project, but say for example there's a project working on something that is skin contacting for an extended period of time. The open source 'team' doesn't include someone with appropriate toxicology knowledge and the design ends up eluting some toxic chemical and making everyone who builds one sick. Someone needs to make sure that people stop using that material for that design and that all of the people who have potentially made one and not yet used it are aware.

The issue about liability for management is a really important topic, since it is these regulatory issues that aim to ensure accountability in the design process- as Printed_Solid points out, these are there to ensure that the regulatory concerns are not

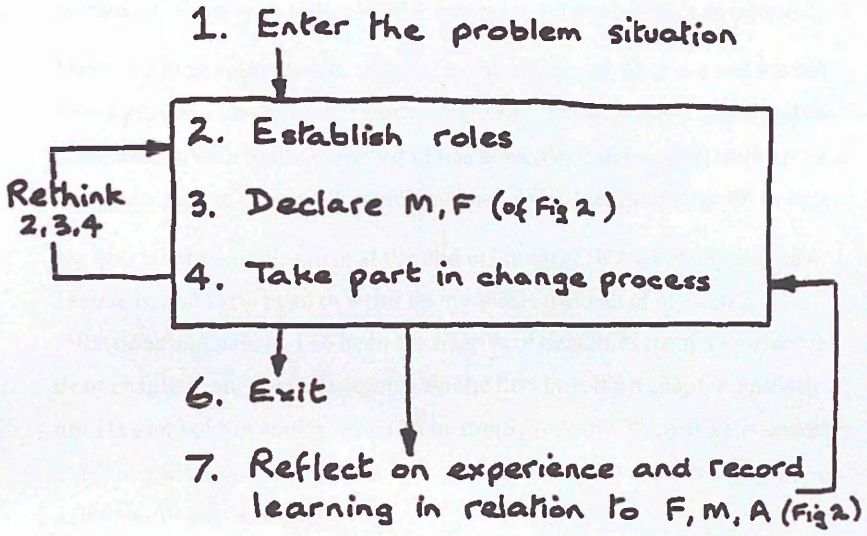
'shortcutted'. The Open Design project means that there is no management structure (potentially)- how does the regulatory agency ensure the standard procedures are followed, in order to ensure compliance?

The idea that Open Design could be used to help with a greater emphasis on human factors / PPI[6] requirements for medical product development is compelling. The requirement that people be involved in the development phase will drive research into the methods by which this could be achieved. This research has a real opportunity here to fill this gap, or form part of a hybrid system here to make this a possibility.

The end

At the beginning of July, I realised that it was time to wind up my active involvement in AIR in order to write up the activity that had taken lace, and also to fit this activity within the wider context of the reading into *Design In Health*, *Design Practice as Research*, *Open Design*, and *Participatory design*.

From Checkland and Holwell's paper 'Action Research: Its Nature and Validity' (1998), the following is a diagram of the Action Research process:



The cyclic nature of the action cycles in the Action Research process can be seen from this diagram. The diagram acts as a flow chart, with the action cycles following the steps 2,3,4,7 > *rethink 2,3,4.*

In this document, the action cycles have been the pre-planning (the reading), then the 'alpha' cycle, 'beta' cycle, and the last 'live' cycle- which loosely translates as:

- pre-planning, assumptions & preconceptions (December 2011 – January 2012)

[6] Public / Patient Involvement

- Action cycle 1 'alpha' development (February 2012 – May 2012)
- Action cycle 2 'beta' development (May 2012 – November 2012)
- Action cycle 3 'live' development (Novermber 2012 – July 2013)

At the end of the final action cycle, and chosen due to project constraints (I have to finish this PhD) rather than the work is 'finished' the project is wrapped up. The participants who have posted the most in the space, and really championed AIR have been made into administrators for the site. Here is a copy of the email that I sent to Ronnie and Amber letting them know the state of the site, and their status regarding the work they have published (sent on the 1st August 2013):

> Hello both,
>
> Firstly, I wanted to say a massive **thank you**.
>
> Seriously, without both of your input over the last year or so this PhD would have been DOA- at least, not in this current guise. I must also apologies too - since I've not been able to dedicate the time I wanted to running AIR in the manner that I initially imagined I might be able. The funding for my PhD meant that I have had to work for the research group, and combined with writing, publishing, and becoming a Dad (twice over!) *and* having to finish within my 3 years (it's common to go over, but I'm only funded for 3, and with kids, a wife & mortgage going over isn't an option!).
>
> There is a little something in the post to say thank you from me and Rachel. I have prayed a lot about this work, and to have those prayers answered so categorically with both of your input has been a massive encouragement- as have your prayer requests Amber, and your daily devotionals on FB Ronnie.
>
> My PhD is set to *finally* finish at the end of January... it's when my last pay cheque is, and I still need to write up my thesis from all of my notes, reflections and papers. I've been set a series of deadlines from my tutors for draft chapters, and I've just completed the first one. It's a chapter a month until the end of November, when I'll be done (in draft). Then, it's December to correct & collate, and January for the viva. Phew. It works out about 1,000 words per weekday!
>
> As such, I'm going to need to take some time out from AIR. I'm going to focus on my writing from the beginning of September - and I've been working hard to try and optimise the dispenser in the background. I've changed out the software on the printer, tried different chemical treatments, and also different materials. I've printed close to 50 dispensers, and have ironed out a couple of bugs. I want to make sure that both of you end up with dispensers that work for you.
>
> However, what next? What do we do with everything that we have accomplished?

The first step is that you're both administrators of the AIR webspace now. The content is shared amongst us all, and there is no protection on the ideas, apart from the blanket Creative Commons licence. In this final month, I'm going to concentrate on production of the enzyme dispensers for you both - and also getting those files and information in the webspace, for you both but also the wider community. From September, I'll step back, so I can reflect on the last year or two, and write up my thesis. I'll obviously check in on the site, clear out the spammers, and be in touch, but I'll stop developing the dispenser.

The site is yours to tinker with, invite people to, carry on... although I wanted to see whether you would be interested in revisiting some of these ideas as business opportunities at a later date? It's just a thought, but we could exploit 3D printing, in a similar way to the prototypes we have at the minute, or by using a professional service like Shapeways to produce 'to order' dispensers in more exotic materials like ceramic, stainless steel, silver, etc. The beauty of doing it this way is there is no expensive investment involved upfront. Perhaps something to think about anyway.

I'm going to try and present the site to the CF Trust here in the UK, to see if more people might be interested

I also wondered whether you might be interested in another thing I had to organise as part of my PhD. At the beginning of July, I haloed to organise a 24hr inclusive design challenge in association with the Royal College of Art here in the UK - a prominent inclusive design advocate called Julia Cassim (who has been involving people in the design process for a couple of decades now) co-organised the event. We brought together CF clinicians, and people who live with CF, and put them in teams with designers. Then, they had 24hrs to design and produce concepts! The people who have CF (we had parents /carers, and sadly the lady with CF who was going to take part in one of the teams had to go to hospital on the morning of the challenge) and the clinicians were intimately involved in the process, and the results speak for themselves! Have a look at one of the concepts that was featured on the Cystic Fibrosis Trust website:

https://www.cysticfibrosis.org.uk/news/latest-news/judges-blown-away-by-cystic-fibrosis-care-app.aspx

The ideas are being taken forward into products - both Blown Away and Geoff the CF bear. Very exciting stuff!

Feedback

As well as wishing to thank both for their participation, I also asked the participants for some anonymous feedback about working in AIR. The positive feedback:

- Product ideas Addressing current Cystic fibrosis needs – seem more relevant to those who use the products, as they help with idea generation.
- New ideas are easier to expand on and weed out due to community's experience and familiarity with community specific needs.
- Less time is wasted trying to understand the user group and it's needs, as the design team is the user group.
- Design details are met sooner, such as number of enzymes that needed to be held for a day's worth of travel.
- real life testing of the products. Testing the medicine cabinet has improved my correspondence with my medications.
- Some ideas need to be worked through more before those testing the reap the benefits, but as we work together through design and trial, each of the products will help everyone who participates in AIR.

The positive feedback highlights the genuine participation that was facilitated by the process. The fact that through the design process, the participant felt able to critically reflect on their own treatment regime, and their own methods by which they organized their management (the portion relating to their medication) is a sign that the mutual learning involved in collaborative design was apparent (the participants were learning something about their own situation *through* design, as well as the designer learning something about the participant's situation).

The fact that the community can judge the efficacy of the ideas quickly speaks to the theory surrounding the use of crowds, and how these can be a useful way of developing often complex ideas. Suroweicki in his book *The Wisdom of Crowds* (2005), Leadbeater in his book *We Think* (2009) and ES Raymond in 'The Cathedral and the Bazaar' (2000) all discuss the notion that the crowd, when properly equipped and motivated can successfully create and drive a development process. It is interesting (and good!) to see that the participants felt this happened in AIR.

The point highlighting the shortening of the research phase (in that the design team spends less time trying to understand the user as they are one and the same) harks back to the reasons for including people in the design and development of medical product prototypes, since the advantages of utilizing that deep lived experience are key.

Feedback was also given that was more critical:

- I think the real struggle with these projects were deadlines and timely feedback.

- Some of the projects are very slow moving due to lack of involvement overall.
- This can be improved by a number of ways. If there is some sort of reward for involvement, or steady involvement in the projects I think people would participate more.
- This was hard to do with voluntary involvement, but I think if stricter deadlines were in place the projects would have a steadier pace.
- More group work weekends with more participants would also benefit the progress of the projects.
- Also, once the group agrees to focus on one project, it may be beneficial to set project goals, for example week one is exploration and research, when everyone brings ideas and specifics about the project to the board. Week two can be use scenario discussion, what do we do now, and where does it need improvement? And so on through the project. This way people will have an idea of what is coming next, and how involved they will need to be.

The pace of development was difficult to sustain over such long time periods, especially since the focus of the PhD activity was rarely solely able to be focused on AIR- there were always other pressures on the design practice, from writing papers, to organizing the 24hr Design challenge, to work within the UCHD research team (not to mention, having two children during the PhD timeframe!); and this is just the pressure on the researcher- the collaborators are all busy people, with Ronnie running a business and having a young family, Amber looking for a new job (and getting married, moving house during the project timeframe). Suroweicki discusses the difficulty involved in sustaining collaborative activity, and this was very evident here. A learning point from this research is definitely that when undertaking such a large project space has to be put aside to *concentrate* on the design practice alone, with the reflection, writing and dissemination happening *after*.

In the case of the PhD, if I had the time again (and in an ideal world), I would have delayed writing until after the case study had finished; not writing to attend conferences or disseminate results until after the research was conducted (except perhaps for the PDC doctoral consortium, which was particularly valuable in helping to shape the research). Or, if this implementation of Open Design was to be taken forward by a company, I would advise that the person hired to facilitate the design activity *only* have that responsibility. This way, the designer will have the maximum amount of time to keep abreast of the conversations and development happening at any one time, and be totally committed to driving the collaborative activity in the site.

However, extending this PhD by a year was not possible due to budget constraints – and as such the research is presented here in this Reflective Log. The research and writing has been undertaken over a period of 3 years 2 months, excluding a 3-month secondment to a Research Associate post at Sheffield Hallam University to work on a different (but related) project to the PhD. The feedback about the setting of project goals is a very good point, and definitely something that should be implemented if this Open Design approach were to be used by a corporate entity, or if this research was to be conducted again.

Incentivising the design activity could be a powerful motivator for action, but I've been involved in a research project that was struggling to attract a community of people living with diabetes to an online design forum, and a lesson learned from that project was that incentives do not necessarily work- there for, this experience tempers the suggestion above. However, my experience previously during the diabetes project was in trying to motivate entirely unmotivated individuals – here incentives would look different, since the participants are already working in the space. The nature and type of incentives would require careful thought, but the fact that the participants raised it here means that they were perhaps left wanting more from the space, or that their time was more valuable than the process of working in AIR made them feel.

The feedback also asked whether there were points for improvement / general feedback:

- The Internet is a great way for those with Cystic Fibrosis to collaborate! It also opens the door for research to expand beyond geographical boundaries.
- I think a few things we could use more of in the AIR project are videos. Product testing videos are great, as well as possibly video group conferences to talk about the products that we are testing. People have a way of talking with there hands, gesturing motions while explaining how things work, or didn't work for them,, so I think incorporating video could help a lot.

The first point is really great to see- the benefits of Open Design in enabling participation were not lost on the participants. The diffuse nature of the design activity enabled genuine participation in the design process- and this was felt and reflected by the participants / collaborators.

The second point about the use of Video is perhaps linked to some of the other points regarding timely communication. The suggestion of more 'face time' (video calling, not the Apple service) makes a lot of sense in the way the participant means... the act of discussing an idea verbally, with hand gestures and such means that more of a complete sense of the idea might be communicated, rather than annotated sketches

that are put forward in AIR. The use of video uploaded to YouTube was a powerful way of aiding the sensemaking between the collaborators in the web space, and also for communicating the status of prototypes at various stages. However this communication is all 'one-way', relying upon a discussion in AIR to delve into the meaning.

The use of videoconferencing tools (such as Google Hangouts) would be an interesting addition to the underlying infrastructure of AIR, perhaps even facilitating the Future Workshop activity. However, the issue of communication across time zones persists- perhaps scheduled calls, or open hangouts at particular intervals might ensure a more convivial atmosphere for the design activity. A good suggestion, that.

Feedback summary

Fundamentally AIR and the Open Design methodology that was used resulted in the genuine participation of a small (but committed) community of people with Cystic Fibrosis in the collaborative development of medical product prototypes.

However, there are significant areas that this activity could be improved upon- especially as since I pulled back from the site, the activity has ceased and AIR is dormant.

The feedback suggests that the I as the facilitator needed to grow the community further, and that perhaps 18 months is not long enough to bring the community from a cold start to fully self-sufficient. However, the work done so far remains intact, and there is every potential that AIR could be restarted once the hard slog of writing and dissemination is over. Perhaps with a new partner in the CF Trust- who knows.

This lack of communication can be perhaps traced to the tension between the design role, and the research one- in designing, I was not necessarily researching- in researching, I was not necessarily designing. The research component was aided by the fact that the activity is recorded as everything is published to the site- encased in Amber, as it were. This makes reflection easier, since it can be pored over at a later date.

This also makes verification easier, since a third party can visit AIR, see for themselves the conversations that happened, and even leave with a copy of the digital prototypes to produce for themselves.

Action Research

The use of Action Research as a guiding methodology for this research through design practice is deliberate. For instance, the epistemological stance that the collective act of sensemaking (around life with Cystic Fibrosis) is a social constructionist activity, and the act of *making* a prototype as a response to this is a realist endeavour is compatible

with the use of Feminist Standpoint Theory to frame the researcher's (my) frame of reference for approaching this work.

For instance, in recognising my standpoint at all times, especially when submitting work for verification amongst the collaborators or representing our work to third parties (at conferences, etc) then the requirement that I reflect on the roles of the participants is kept to the fore.

Amber at times played the role of facilitator, champion and designer. As best as I was able, I provided the space for these roles to flourish. The tools available in AIR are crude Open Design tools, but Amber was able to use them to initiate discussions (sometimes external to AIR), post ideas (with deep personal meaning, or in a response to another person's stimuli).

Cynically, one might view Amber's involvement as a given in this project. For instance, quoted in Cruickshank and Atkinson (2013) is Woods (2009):

> 'There is no crowd in crowdsourcing. There are only virtuosos, usually uniquely talented, highly trained people who have worked for decades in a field'
>
> Woods, D. (2009). The Myth of Crowdsourcing Crowds don't innovate--individuals do. Forbes. Retrieved from http://www.forbes.com/2009/09/28/crowdsourcing-enterprise-innovation- technology-cio-network-jargonspy.html

This view might suggest that Amber's participation in this project fulfils this quote, by the fact that she is an interested party.

Personally, I do not share this view (in it's entirety). Amber may very well have been attracted to participate in AIR because she is 'a virtuoso', and 'uniquely talented' (compared to others) – insofar as her obvious passion and training in design manifests itself in the sketches and ideas put forward. However, not every person is a 'Pro-Am' or 'Lead User' by definition. Some are content to purchase and use a product, some may well be inclined to tinker with or customise a product- but all benefit from the open invitation to participate through the work of the Lead Users, customisers and even 'average joe' consumers that have a hand in shaping the product at the end.

AIR needs Lead Users. Amber is a Lead User – and would not have worked without her input; similarly AIR needs champions who don't necessarily identify as designers... Ronnie has been an integral part of this research. All who participated in whatever way have meant that AIR has been a successful space in which to collaboratively participate on open source medical product prototypes, and these roles were key in that.

The Contribution to Knowledge

For more information on this subject, it's best to have a look at the Study, and Conclusion chapters in the thesis.

The use of Action Research as a methodology to guide the process outlined in the reflective log, and the epistemological understanding of my position in the research and the way sensemaking and the prototyping activities happen- dictates the type of knowledge created.

The knowledge is situational, being generated in a specific timeframe and distributed amongst the artefacts (including the web space AIR), and people who took part. The reflections of the researcher, including the preconceptions listed at the beginning of the document can be examined against the web space (AIR) as a record of the events. This ensures rigour in the process, and guards against the research being simply a piece of reflective writing.

Assumptions vs Reflections

Below are the assumptions listed at the beginning of this document, with a brief outline incorporating the reflection on these post action.

1. That this will be an interesting and engaging way for people to participate in the design process
    a. People will want to participate... if I have a *champion*
        i. Assuming the lessons learnt from Diabetes Phase Zero are applied
2. The process will come up with some novel concepts
3. That cultivating and sustaining activity will be hard work (Suroweicki, 2004)
    a. The correct tools should be employed – Suroweicki suggests Wikis
4. In order for people to engage and work with me in this, the production value of the work must be high
    a. People must feel welcomed into the project, and that the work is serious
5. The right tools need to be supplied to enable participants to express their ideas
    a. Or, that tools need to be supplied *at all*
    b. These tools are an extension to the idea of *Toolkits for Innovation and Design (TKUID)* used in Mass Customisation
    c. These tools are comprised of a physical aspect, *and* software
        i. Pens & 'traditional' design tools
        ii. MineCraft Print & SketchUp
    d. People will find creative reflection difficult

1. An interesting and engaging method for participation.

This turned out to be largely the case- the feedback didn't say the project was boring or that it was uninteresting or unoriginal. However, this was still a *difficult* activity to foster, even though the barrier to participation was lower. From my own work (Diabetes phase Zero, see the Study chapter in the thesis for more info) I knew the need for a champion, and after the sterling work by Ronnie and Amber (acting as strong community advocates) the level of activity increased.

2. The process will come up with some novel concepts.

The concepts to come from AIR are certainly novel – they fulfil niche applications that are often overlooked by traditional Med Tech because of a small market, or perhaps a low-revenue device that is perceived to be 'good enough'- the pill box for enzymes being a prime example.

3. That cultivating and sustaining the work will be hard.

The work was most certainly difficult to sustain. This was for a variety of reasons, but the main one being that AIR hadn't reached a critical mass of participation as yet. Balancing the full-time requirement of designing for and in AIR, as well as research overhead (and having a family) was super-difficult. In the future, when planning these activities, the design component must be given primacy.

4. High production values.

This is a more difficult assumption to categorise, since the success or failure of the project depends on perhaps more fundamental factors (e.g. could I recruit anyone to participate?). However, the items that were overtly discussed with participants (the AIR site, and the toolkits) were uniformly received positively. This suggests that the production values were appropriate for the work that was done here.

5. The right tools for the job.

The toolkits that were sent out for people to use appear to be abject failures in this case. Nobody overtly used them (as in, said so), although I suspect that some of the drawings that Amber posted had an element of the toolkits used in them. However, the toolkits were dual purpose, in that they were also a gift to thank the person for agreeing to sign up for the project. In this regard, they appear to have been a success- the toolkits were all graciously received. In terms of other tools, notable by its absence in the list above is the mention of AIR itself being a tool – the web technology supplied by Ning™ that enabled the posting of video content for sensemaking, through to the discussions about prototypes and workshop events. In this regard, AIR was a success... although far from optimal. The other esoteric tools to lower the barrier to 3D printing and CAD data (MineCraft Print and Sketchup) were not broached, as too few of the

participants took to designing with these tools. Even though they are both more simple than lots of commercial CAD software, both still have a steep learning curve. The shared tools that the participants and me used became a common language with which to communicate, rather than introducing something new.

Summary

This document contains a chronological record of the activity in AIR, the main case study. The events recoded here can be matched with the other publications in the Appendices, online via AIR, and also in the various chapters of the thesis.

This Reflective Log describes a piece of research through design practice- and as a generative piece of design does not seek to present a 'Law' for generalisation in the vein of the Natural Sciences; rather it presents a specific situation, with a specific group of actors, conducted in a specific manner with regard to a specific methodology of research, and methodology of practice.

The work is intended to inform design practice, and I would imagine that the findings would be of interest to medical product designers, Open Design(ers), design managers, policymakers, and perhaps even advocacy groups. The specific outcomes recorded could therefore inform future design practice, or become the basis for other, more empirical modes of research by others. In this way does the knowledge described here constitute research, and a unique contribution to knowledge.

9.2. Appendix B - *PhD Methodology Diagram*

This diagram is the full size version of the diagram in Figure 9, p 91.

1 page (A3, fold out).

2012 2013

J F M A M J J A S O N D J F M A M J J

'α' Development | 'β' Development | 'Live'

RF2

Research Framework 2
Change to the main case study... a single, in-depth Open Design project.

'α' **Preconceptions**
Recorded In accordance with the requirements for Action Research.

AIR created - using Ning™
Colours, logo and styling created

Toolkits Produced

Static Web Space
Static website created, explaining the project & used for recruitment.

'α'

'β' **Recruitment**
Recruitment attempt using PPI & Involve. Unsuccessful.

'β' **Recruitment**
Promoted post on Tumblr. Promotion and recruitment.

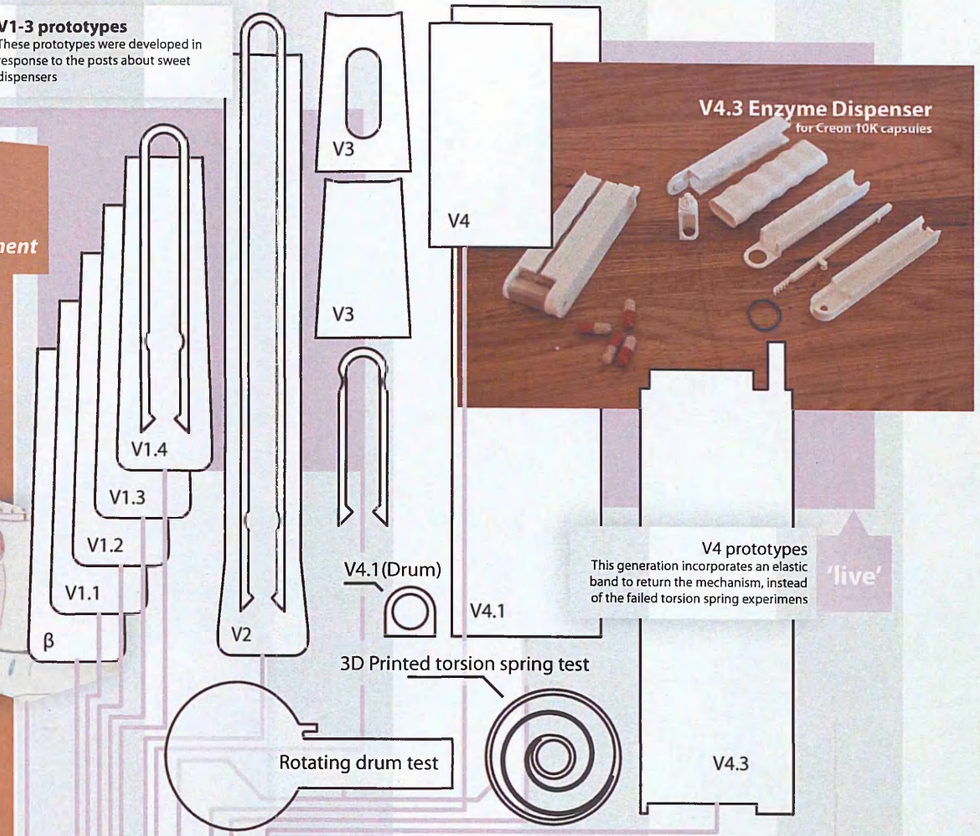
'β' **Toolkit**
Posted to Ollie in respons
Tumblr. Ultimately no response

PDC 2012
Doctoral Consortium
Refining the PhD theory, and practice
'β'

Future Workshop
Descrete action cycle within beta development phase.

Future Workshop
Planning | Review | Imagine | Implement

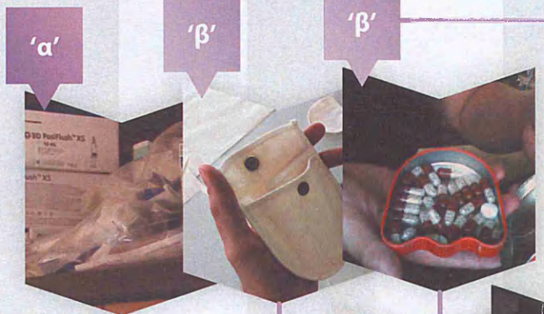
'live' **V1-3 prototypes**
These prototypes were developed in response to the posts about sweet dispensers



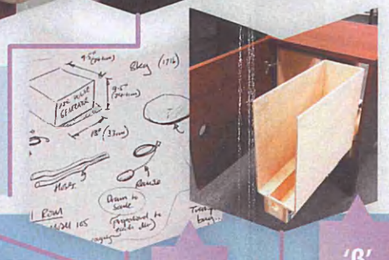
V4 prototypes
This generation incorporates an elastic band to return the mechanism, instead of the failed torsion spring experimens

'live'

'α' 'β' 'β'



'β' 'live' 'live'



'β' 'β'

Fashion Accessories Development

Enzyme Dispenser Development

Closed-source Development

Treatment Cabinet Development

'α'

Holly Recruited
Toolkit & AIR refined

'β'

Amber Recruited
Treatment Cabinet & Enzyme Dispenser

'α'

Ronnie Recruited
Treatment Cabinet Posited

Action Cycles

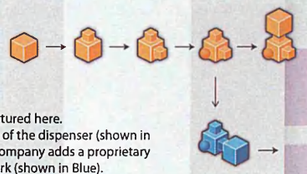
The action cycles are broadly concentrated in the three development phases of AIR - these being 'alpha (**α**)', 'beta (**β**)' and 'live'. Each of these has planning, action and reflection stages.

However, there are also other action cycles beyond **α, β** & **Live**.

The Future Workshop represents a separate action cycle, with it's own planning, action and reflection. Similarly, the Pharmaceutical conference call on 6th March 2013 is an action cycle, resulting in the development of possible business models.

'live' **Pharmaceutical Conference Call**
Discussion of AIR with the enzyme manufacturer. The development effort of the dispenser was highlighted - the process of Open Design being the focus of the call.

The result of this call was the development of prototype business models that could be used for AIR, or projects like it.



One of these is the strategy pictured here. The open source development of the dispenser (shown in Orange) continues, while the company adds a proprietary technology as a 'fork' of the work (shown in Blue).

S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D

RF 1

Secondment to UCHD - working on the 'Phase Zero' project
Online Participatory Design work.

RF 2

Writing Up

9.3. Appendix C - *Ethics – Informed Consent*

This form was sent to all participants who received a toolkit, with the information duplicated on a static website that was used to inform participants who came to the project by themselves once AIR was fully open. This static website can be found at:

http://airdesignspace.businesscatalyst.com/index.html

Working in AIR

Dear

While we're working on this project, there will be ideas posted on AIR by yourself, and others. These are available to see by other people participating in the project, but not the whole Internet. If you want to take part, then you agree to be polite to other people who are participating, and also to not share any ideas outside the AIR group at this time. Eventually, the plan is to open up the space so anyone can come and see what has been going on and to participate, but when that time comes you have the choice to remain anonymous, or to be recognisable.

The work will be stored in the sketchbook that comes in your welcome pack, and in the AIR website. Only people who have access to the website can see the work that is posted, and you can choose to remain anonymous in the AIR space if you like.

1. Sharing with researchers and people working in design and healthcare

The findings of our research will be shared with researchers in Sheffield Hallam and other Universities and people who work in design, healthcare and related professions. This may be in the form of academic papers, presentations and talks, trade or professional magazine articles, and electronic forms such as CDs and DVDs.

2. Sharing with the general public

I would also like to share the design work we do together with a wider general public audience, such as, newspaper articles, public presentations and talks, and web sites. At the end of this project, the work we produce will form part of an exhibition- you can decide whether you are named in the exhibition or not, and you can change your mind at any point in the project.

Being anonymous

If I include quotes from the AIR website in papers, and you would like to not be recognisable, then please use a nickname or equivalent in your profile on AIR. That way, if any of your ideas are to be shared, then you would automatically not be recognisable. If you initially decide that you don't mind using your real name, but change your mind then that is fine- simply email and ask that you would prefer not to be recognisable in any publications outside of the AIR website.

Being recognisable

Some ideas posted in the AIR website might be used in which you can be recognised. I might also use text quotes from what you have said or notes that you have shared with your real name.

Would you like more information?
Please feel free to contact me if you would like any more information about the project, or if you would like to go through anything written here. You can reach me at:

Matt Dexter

Room 9220
Cantor Building
153 Arundel Street
Sheffield
S1 2NU

0114 225 6745

matt.dexter@shu.ac.uk

Project name:
Open Design for Cystic Fibrosis

✂ .....

Please answer the questions below, sign, and return the form in the self-addressed envelope.

I agree to participating in this design and research project: Yes/No
(Please circle)

I agree to the designs produced by me being used in research and professional publications and presentations (please tick one):

Either ❑ Anonymously **Or** ❑ Recognisably

I agree to the designs produced by me being used in general public publications and presentations (please tick one):

Either ❑ Anonymously **Or** ❑ Recognisably

Your name:		Your telephone:	
		Your email address: (optional)	
Your signature:		Date:	
Matt Dexter signature:		Date:	