

CLOSING THE LOOP: TAKING EVIDENCE-BASED DESIGNS INTO MANUFACTURE

Matthews E, West J, Halls S & Coleman R

*Helen Hamlyn Centre (HHC),
Royal College of Art (RCA),
London SW7 2EU
www.hhc.rca.ac.uk*

Collaborations between designers and clinicians can deliver better, well-researched products for healthcare, but the benefits can only be realised once such evidence-based designs are taken through to manufacture. Bringing together the research, design and clinical disciplines with the industrial culture of product development and manufacture adds an extensive stage to the process. The importance, complexity and cost of this is easily underestimated. A case study of a new resuscitation trolley exemplifies some of the challenges involved in taking evidence-based designs to manufacture. Potential difficulties in bridging the different cultures of the collaborating partners are highlighted, as well as some of the solutions that have been developed to address these. Further, we address the crucial question of how to fund product developments rooted in academic design research, and how we resolve the associated conflicts between the 'not-for-profit' nature of research funding and the commercial imperatives of industry partners, played out in the field of Intellectual Property.

Introduction

Smaller healthcare manufacturers often lack the resources and expertise to undertake the scale of research required to underpin evidence-based design. Commercial constraints can drive manufacturers to take tactical approaches to new product development, based on the best guess they can make about market trends and the 'Voice of the Customer'. This contrasts starkly with the measured, diligent and time-consuming approach required to carry out the user-focused research necessary to provide the evidence base for designs for the clinical environment. In the commercial world, such a research approach proves not only highly expensive, but too slow to deliver results if a company is merely trying to react to emerging market trends. So commercial design research tends to be short-term, increasingly leading to sound-bite briefs that design agencies try to respond to within ever shorter deadlines. Standing back strategically to develop a knowledge base, from which a more proactive approach can be

taken to product development and marketing strategy, is vital for design in healthcare, (Clarkson *et al*, 2004), and demands an approach and timescale that fits far more naturally into the academic research model.

As a consequence, commercially-originated product designs and development rarely have a proper research underpinning. Even where industry takes up a research output and implements it, this often takes place in the absence of the insights of the researcher, so the interpretation may lose some of the subtleties of the evidence-based design. A crucial element is thus neglected, which can act as a barrier to the introduction of evidence-based designs to clinical environments.

The stage from design solution to manufacturable product is not recognised as part of the research process, and is unlikely to be readily funded by traditional sources for academic research. Even if academic research funding sources were to be made available, a product development carried out by academics alone would be unlikely to achieve the commercial and manufacturing focus for it to be successfully marketed.

Case study

The research and design development of a new resuscitation trolley is discussed in another paper for this conference. The focus of this paper is on the subsequent steps in the full process to manufacture. Beginning with the cross-over point between design development and productionising—the fabrication and validation of proof of concept prototypes—key steps included: (1) building a sound business case, identifying an appropriate industrial partner and negotiating a mutually beneficial agreement; (2) designing for manufacture; (3) designing and funding clinical trials; and (4) positioning and realising the final product as the result of an evidence-based design process.

1) Building a sound business case, identifying an appropriate industrial partner and negotiating a mutually beneficial agreement

Any industrial/academic collaboration must play to the strengths of its partners. Constructing a sound business case is vital in the commercial world, but is not always within the realm of expertise of the academic. The research and development of the resuscitation trolley was presented on its own merits, with little business context. The prototype was exhibited and tested in September 2006. This attracted press interest from the design world as well as the clinical world, leading to the design being entered for the prestigious Medical Futures Innovation Awards, where against 1200 entries and 30 finalists it won not only Best Medical Device in the Anaesthesia and Critical Care category, but also the Overall Award prize in its class. The interest from manufacturers grew to the extent that they constructed business cases of their own, often using confidential data, to secure internal investment. This step would have been more time consuming and less credible had it been a task for the academic partner.

A long list of companies with an interest in resuscitation was built up during the initial research, and expanded through stakeholders' contacts. Identifying the correct partner is clearly crucial in securing a product's successful route to market. A number of companies were contacted or had expressed an interest in the commercialisation phase, so the academic team agreed on certain criteria (e.g. manufacturing capabilities, design engagement, quality of existing product range, ease of communications etc.) to assess partner suitability. Further meetings and site visits enabled a final partner to be selected from a shortlist.

The new design was developed entirely by a non-commercial collaboration and funded by

the National Patient Safety Agency and Helen Hamlyn Trust. Neither of these institutions was dependent on the commercial success of the design for their future funding. This removed the need for hard-line negotiation over the profit split with the manufacturer; the intent instead was to build a longer term involvement by both parties to ensure the success of this, and potentially other projects. The aim in this particular case was to retain ownership of the intellectual property and licence this to the manufacturer, allowing exclusive manufacturing rights in the UK and Europe. This was important, as it allowed the freedom to pursue other future potential avenues of development with other companies in different market sectors.

2) Designing for manufacture

The agreement between the two partners must be clear and up front in order to facilitate the working relationship. Clear communication at all stages has been important. The industrial partner needs to understand the subtleties of the thinking underlying the design and endeavour to maintain it, whilst the academic partner (maintaining design authority and defending critical features of the philosophy underlying it) must respect necessary changes for mass production.

The Medical Futures Innovation Awards were timely in this instance, as they facilitated the initial relationship between the industrial partner and the collaborating institutions. It fostered an enthusiasm for the project, and allowed for good communication between designers on both sides. In practice, design for manufacture never seriously compromised the initial design intent, as the collaborative design team were involved in every manufacturing decision, often down to the minutiae of dimensional tolerances as well as materials selection. Because of the continuing research involvement, it was feasible to involve end users in this decision making process.

3) Designing and funding clinical trials

Objectivity is crucial for a clinical trial to stand up to the rigour of academic analysis. The academic and clinical expertise of the collaborating institutions proved invaluable in clearing the necessary ethical hurdles for a formal clinical trial. As the hospital had been involved in the project from the outset, a robust clinical protocol was developed relatively quickly, requiring a minimum of revision and resubmission to the Ethics Committee prior to approval, as the ongoing research had been well communicated throughout.

Had clinical trials been led by an industrial partner, their objectivity may have been compromised, leading to conflicts that could complicate and delay the approval process. For example, there could be a temptation to minimise sample numbers and trial duration in the interest of getting the product to market as quickly as possible. The involvement of the industrial partner has simply been to optimise design for manufacture, and provide enough prototypes for the trial. While there is necessarily a clinical lead organising the trials, the nature of the collaboration means that the trials can still provide data which can be used to inform subsequent design work.

4) Positioning and realising the final product as the result of an evidence-based design process.

The broad process outlined in this case study has included three prototyping stages, each more sophisticated than its predecessor, with the user input and critical refinement becoming more extreme as the project progresses toward manufacture. Other medical devices will clearly require different milestones according to the constraints of time, costs, complexity, ethics and

so on. The approach outlined above remains beneficial, provided a degree of sensitivity is shown in the timing and nature of collaboration with manufacturers, clinical staff and end users.

The success of a product in the market place is rarely solely attributable to the quality of the particular design or innovation. A knowledge of the market, timing, contacts with purchasing authorities, logistics networks and so on are necessary to support innovative products. Any industrial/academic collaboration must play to these strengths in order to bring a product successfully to market.

Discussion

A series of factors critical to success have been established, including establishing a good relationship with a manufacturer, communicating and negotiating the primacy of design intent, building strong links with the collaborating NHS Trust hospital, designing and implementing trials, and supporting the manufacturer in delivering the product to the marketplace. To date all the participants—HHC, Imperial College, St Mary's Hospital and manufacturers Bristol Maid—have supported this process from their own resources. With real costs well in excess of £100,000, not counting trials, funding this crucial gap between conventional research and delivery of a product to the clinical environment presents a major obstacle to the implementation and uptake of evidence-based design in healthcare.

One area where knowledge transfer between academia and industry was found to be fruitful was in the direct involvement of the end user, including clinical staff from ward through to board level. These techniques have typically been developed in academia and are now successfully delivering benefits in a commercial context. Working with end users can bring inspiration to the design process as well as information to the design brief. In this project, the users who were studied during the design research phase gave important insights that directly impacted on the final design for manufacture.

Finally, perhaps the single most important factor in promoting successful knowledge transfer between academia and industry, is the recognition and acknowledgment of the cultural differences that exist. Whilst the HHC still intends to fully explore the limits of high-ground academic research in Inclusive Design, there is a strong drive, from the founders of the Centre and the Helen Hamlyn Trust, to take research outcomes through to commercial exploitation. For this reason, an academic research group was established to address Design for Patient Safety. New members were recruited with backgrounds in product development and technology consultancy in the Medical Device and Healthcare industry. Crucially, however, relationships must be built with industrial partners whose manufacturing and marketing capabilities provide the final link to the commercialisation of the design outputs of the research. The quality of these relationships is underpinned by a genuine desire to collaborate and combine our working cultures, and the fact that the methodologies of these industries are quite familiar to the HHC.

Conclusion

Whilst design research in its own right is valuable, designs for patient safety can have little impact in the real world unless they can be commercialised. They must be put to the test through prototyping, testing, clinical trials, manufacture and product sales.

The complex processes of research, design and development rely on the strengths of each group to complement the weaknesses of the other. But projects need to be funded.

Traditionally, Research Councils have funded academic research and design work, rather than developing and prototyping new products. The rightful place for these activities has been considered to be the world of commerce. Moreover, as industry traditionally reaps the commercial rewards of manufacturing and marketing products, industry should fund development and shoulder the risks involved. Thus, Research Council funding has not traditionally been available to help that journey to be made.

The question is how development projects which that need coordinated input from clinicians, academia and industry can be ethically funded.

The solution lies in engaging industry, not only for production design and manufacturing expertise, but also for funding. Investment is an indication of commitment, and it is right that the link between reward and risk be maintained.

Design authority needs to be maintained by the design researchers in order to preserve the findings of the user research. It is appropriate, then, that academic funding should also extend into the development stage. A traditional research funding approach is simply to avoid putting money into something that will then benefit a commercial enterprise. But properly controlled, for example by earning royalties from licences to exploit IP through manufacture, there need be nothing unethical about nourishing academic research with royalties earned from the industry that exploits the results of that research.

References

- Clarkson P, Buckle P, Coleman R, Stubbs D, Ward J, Jarret J, Lane R & Bound J. (2004) *Design for patient safety: a scoping study to identify how the effective use of design could help to reduce medical accidents*, Engineering Design Centre, University of Cambridge, UK