insight.
ISSUE No.6

The giant mutant space lizard analogy

Ben Wicks looks at the challenges of chronic wound care

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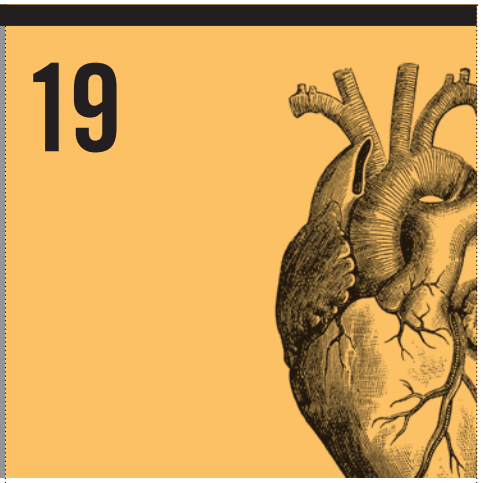
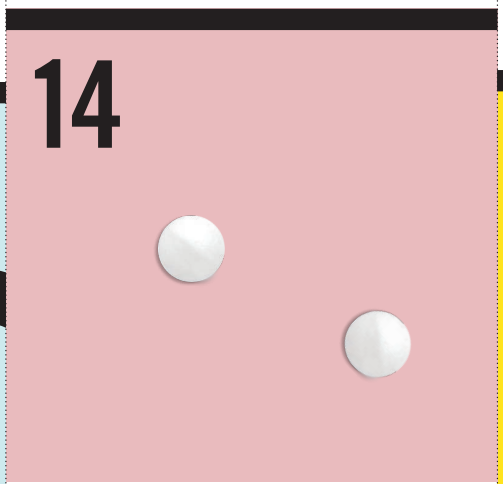


A CHANGE OF HEART

Nick Hitchins looks at the history of implantable heart pumps and the future generations of products that will drive further innovation in an industry that has evolved significantly over the last 60 years.

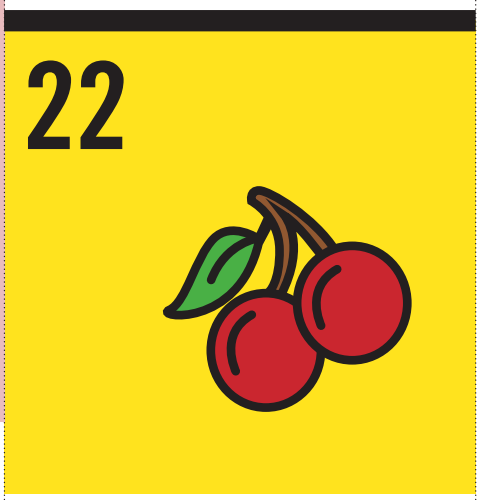
THE 10 PRINCIPLES OF GOOD MEDICAL DESIGN

Dieter Rams established some design principles in the 1970s that challenged him to ask “is my design good design?” These much celebrated principles are still popular today but Paul Greenhalgh looks at their relevance to the medical sector and suggests some changes.



MEDICATION ADHERENCE: A SHORT LITERATURE STUDY ON DESIGN INTERVENTIONS

Poor adherence to medication regimens inhibits the benefits of medicines; this leads to a lack of health improvements for patients or, worse, a detoriation in health. Thomas Grant examines the latest research around this hot topic and looks at the possible design interventions.



ADHERENCE AND...

CARING
Through an interview with a COPD patient, Martin Bontoft looks at the context of the patient’s condition and the very personal barriers to better adherence.

FUN
In another interview, Martin Bontoft recalls a meeting with a mother suffering from diabetes and dealing with two small children and the very real challenges that stop her from taking her medication.

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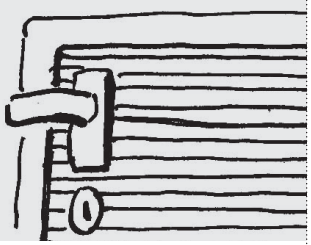

TEAM 'TOONS

Through the medium of cartoons we explore the funnier side of some of the problems that we see in our industry.

Introduction

BY **DAN FLICOS**

A good proportion of this edition of Insight is focused on adherence. It is a big issue facing the industry and over the years we've been involved in helping to improve adherence or compliance through the work we do. There is no silver bullet unfortunately, but we think that there is scope to improve. At a global scale, if we can make some changes that can have a positive impact on adherence even by just a few percentage points, then we should do it. The temptation is often to look for sophisticated approaches and to overlook the simpler solutions, which we must avoid.

My colleague Thomas Grant has conducted a short literature study on medical adherence to provide a really good overview of the topic and the latest research, while Martin Bontoft has written up the results of two patient interviews that he conducted. In his piece Martin looks at the 'other stuff' going on in the lives of patients and the impact this has on their ability and desire to follow doctor's orders, highlighting the complex context that applies to medical devices.

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Neil Cooper / Tom Brooks / Angela Murray
Designed by: The District

team. medical design and development

WOUND CARE AND THE GIANT MUTANT SPACE LIZARD ANALOGY

BY **BEN WICKS**

If you mention ‘wound care’, many people will assume you’re talking about sticking plasters or Band-Aids for cuts and grazes, since we’re all familiar with this type of wound. Whilst there’s a large global market for treating trauma and acute wounds, there’s a much larger, hidden world of chronic wounds, which are less visible but which cause an immense amount of morbidity and suffering.

Chronic wounds are those which last more than a matter of days, and can sadly last months or even years. The cost of treating and managing these wounds is extremely high, particularly as care is often delivered in the home.

The underlying causes of chronicity (delayed healing) are complex, as we'll discuss later, but problems such as poor circulation, immobility and underlying diseases such as diabetes, are often contributory. Unfortunately, the prevalence of chronic wounds is growing due to an aging population and increasing incidence of type 2 diabetes.

Management of chronic wounds has come a long way in the last 30 years. For example, it is now almost universally recognised that chronic wounds need to be kept moist in order to promote cellular healing, and as a result moist wound healing is now the standard of care in the developed world. Many other methods of accelerating wound healing have been investigated, with varying levels of success, but unfortunately our understanding of wound healing and chronicity is rudimentary, particularly when compared with diseases such as cancer which have been intensively studied for many decades.

So why has wound care research lagged behind? The answer is, in part, due to the very fact that chronic wounds are hidden, both practically and socially. They lack prominence yet sadly cause a huge amount of suffering and are a significant drain on health care resources. The good news is, however, that research into chronic wounds is gaining momentum and is being driven by a growing body of passionate and talented research scientists around the world, many of whom are based in the UK.

Although this research is now ongoing, great heterogeneity still characterises the management of chronic wounds, and the therapies available to clinicians remain relatively unsophisticated, particularly when compared to the high tech tools and drugs used to treat vascular diseases or cancer, for example. The vast majority of wound dressings simply cover the wound and manage the exudate. Even the 'advanced' therapeutic dressings now in routine use tend to deliver a single therapy to the wound, such as an anti-microbial compound (such as silver ions), a pain killer (ibuprofen or acetaminophen, for example) or a physical effect (such as negative pressure). Each of these can be beneficial but it's important to get some perspective on just how unsophisticated these therapies are in the context of wound healing.

SO WHY HAS WOUND CARE RESEARCH LAGGED BEHIND? THE ANSWER IS, IN PART, DUE TO THE VERY FACT THAT CHRONIC WOUNDS ARE HIDDEN...

Let's use an analogy... Imagine the complex arrangement of cells, tissues and blood vessels in the skin as the buildings, infrastructure, roads and services within a city district. OK, now imagine that our city has suffered some serious physical disruption, let's say a giant mutant space lizard has stomped all over the downtown area. Buildings are wrecked, fires are burning, and the place is in chaos.

The first job is to put out the fires and stop the leaking water and gas pipes. Next, the roads must be cleared to establish access in and out of the damaged area. Bulldozers, diggers, demolition cranes and pneumatic hammers will all need to be brought in so that damaged and dangerous buildings can be demolished to make way for new structures. Rubble also needs to be removed so that new brickwork can be laid on solid foundations.

Very similar activities take place in the skin after trauma. Once the bleeding has been stopped, a host of different immune cells will begin to clear away damaged tissues. Enzymes will break down damaged connective tissues before new cells can start to infiltrate, proliferate and repair the damage. New blood vessels will be created to supply the newly formed tissue.

The process of repairing and rebuilding our city is equally complex. Once the initial damage control is completed and access has been established, a massive amount of coordination and planning is required to organise the many different trades and supplies required to rebuild everything from the sewers to the supermarkets. Unfortunately, large civil engineering and building projects are all too often delayed.

OUR UNDERSTANDING OF CHRONIC WOUNDS IS NO MORE COMPLETE THAN THE MAYOR'S UNDERSTANDING OF WHY THE CITY'S REBUILDING PROGRAMME IS BEHIND SCHEDULE.

The rebuilding process is complicated and the repair tasks are interdependent, so it doesn't take much for the entire project to get held up. Perhaps the demolition crews have accidentally demolished some new buildings by mistake, maybe cement is in short supply, thieves have stolen the copper electrical cables, or someone has ordered the wrong sort of drywall screws. Any of these problems will cause knock-on delays across the site; the bricklayers need the foundations to be completed, the plasterers need the drywall to be finished, the electricians need more copper cable to be delivered and so on.

OK, now imagine you're the city mayor and you're coming under pressure to get the downtown area rebuilt as quickly as possible. You've heard about the various different problems and the reasons for delays. You need to do something to help, after all it's your job and people expect you to act decisively and to make things better. Your advisors offer various suggestions: airdropping cement bags across the entire site; banning the use of demolition equipment; carpet bombing drywall screws; or instigating a shoot-on-sight policy for anyone seen carrying copper cable. The problem with all of these interventions is that they're not only daft but they only target individual aspects of a much bigger and more complex problem.

The same is true when it comes to tackling the problem of chronic wounds. The repair mechanisms are complex and involve a series of sequential, coordinated processes. If any one of these processes is disrupted, becomes unregulated or gets out-of-sync, then the natural wound healing process can stall.

Sadly, our understanding of wound healing biology is currently so incomplete, and our therapies so imprecise, that even the most advanced treatments are akin to airdropping bags of cement onto a building site. For example, we know that the level of proteases (enzymes that break down damaged proteins) are often elevated in chronic non-healing wounds, and so treatments have been developed that seek to counteract excess proteases, but — unsurprisingly — they aren't a miracle cure. We also know that excessive growth of pathogenic bacteria in the wound isn't a good thing, so we use dressings that release anti-microbial compounds, such as silver or iodine. Again, these dressings certainly help in some circumstances but not all, and sadly we don't entirely know why or how to identify those wounds which will respond to a particular therapy.

Our understanding of chronic wounds is no more complete than the mayor's understanding of why the city's rebuilding programme is behind schedule. Our current interventions are no more sophisticated.

Today's biomedical scientists do have an astonishing suite of tools at their disposal to help elucidate the molecular and cellular basis of disease. Encouragingly, these research tools are currently being applied to shed light on the fundamental principles of wound healing. More work is needed to build a more comprehensive picture of the interrelated mechanisms involved in chronicity, but as our understanding grows we can expect better diagnostic and therapeutic tools to be delivered.

Finally, the pharmaceutical and medical technology industries need to recognise that wound care presents subtle but important differences from more mainstream disease areas. Not only is the underlying biology complicated and poorly characterised, but price sensitivity is high and the way in which care is delivered doesn't always fit standard business models. Recent history contains several examples of where pharma and medtech companies have overlooked these differences and been left wondering why their products and therapies failed commercially. Thankfully, there are also recent examples of products which have been clinically and commercially very successful in wound care, most notably in negative pressure wound therapy (NPWT). These successes are helping encourage on-going investment in wound care R&D.

The challenges of raising the standard of chronic wound care are considerable. But those who are willing to work hard, to understand the biology, to think creatively and to understand the world of their users, patients and payers, will continue to advance care and improve the lives of many millions of patients whose suffering is often out of sight and out of mind.

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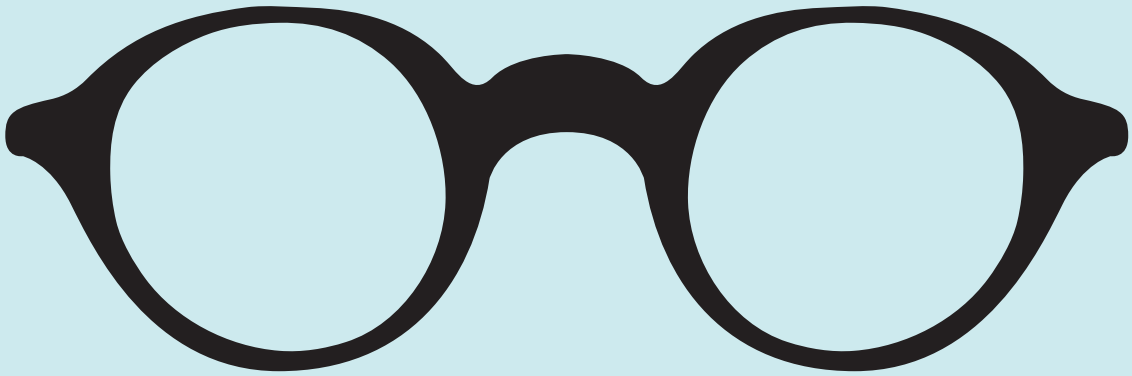


The 10 principles of good medical design

BY **PAUL GREENHALGH**

Medical product design carries a huge responsibility, as we're developing products with which millions of people worldwide will have to interact on a daily basis. Products that quite literally have the opportunity to change and save lives. Products which may remain on the market for ten years or more, influencing the way people manage their health or the health of others.

Medical product designers must therefore make decisions that will stand the test of time, and that suit the broadest spectrum of users as these will be people who often can't exercise choice over the products they are offered. How do we ensure that the decisions we make result in well-designed products? We're not the first generation of designers to have had this dilemma. I've written about one of my biggest design influences, Dieter Rams, before in Insight (http://te-am.co/PGinsight3) and feel that once again medical product designers can learn much from his approach to design.

Towards the end of the 1970s, Dieter Rams was becoming increasingly aware of the influence he was having on the world around him through the products he was creating. Describing the world as "an impenetrable confusion of forms, colours and noises." he asked himself an important question: is my design good design?

To help inform the design decisions he was making, Rams captured what he believed to be the ten most important principles for what he considered was good design.

I've taken a fresh look at these ten principles and reflected on their relevance to the sector we serve — medical product development.

I'D LOVE TO KNOW WHAT YOU THINK OF MY INTERPRETATION OF THE TEN PRINCIPLES. IS THERE ANYTHING THAT YOU WOULD ADD?

1 GOOD DESIGN IS INNOVATIVE

The possibilities for innovation are not, by any means, exhausted. Technological development is always offering new opportunities for innovative design. But innovative design always develops in tandem with innovative technology, and can never be an end in itself.

Innovation in such a risk averse industry can be challenging. Innovations from other analogous industries have huge potential for improving the usefulness of medical devices, but we shouldn't add technology for the sake of it. Innovation should focus on addressing real needs and harnessing the benefits of new technology, not forcing it into products where it's not needed.

2 GOOD DESIGN IS USEFUL

A product is bought to be used. It has to satisfy certain criteria, not only functional, but also psychological and aesthetic. Good design emphasises the usefulness of a product whilst disregarding anything that could possibly detract from it.

Medical products are designed to do a very important job. They are neither ornamental nor objects of desire. Good design focuses on identifying and addressing the key 'jobs to be done' in a way that is compatible with the lives of the people who use the product.

3 GOOD DESIGN IS AESTHETIC

The aesthetic quality of a product is integral to its usefulness because products we use every day affect our person and our well-being. But only well-executed objects can be beautiful.

The way a medical product looks and feels can influence the emotional connection with its user. Fundamentally, aesthetics should be driven by the function of the product but where appropriate can be used to engage a user and evoke a specific emotion.

4 GOOD DESIGN IS UNDERSTANDABLE

It clarifies the product's structure. Better still, it can make the product talk. At best, it is self-explanatory.

A medical product must be intuitive on first and repeat use. It should be easy to learn and easy to remember. It should achieve a high level of safe usability throughout its lifecycle. It should be respectful of the varying cognitive abilities of the user.

5 GOOD DESIGN IS UNOBTRUSIVE

Products fulfilling a purpose are like tools. They are neither decorative objects nor works of art. Their design should therefore be both neutral and restrained, to leave room for the user's self-expression.

A medical product should integrate seamlessly into the user's lifestyle. Whilst there is a requirement to provide safety critical information and guard against incorrect use, consideration must be given to how the device will be perceived in the context of the 'other' products surrounding the user.

6 GOOD DESIGN IS HONEST

It does not make a product more innovative, powerful or valuable than it really is. It does not attempt to manipulate the consumer with promises that cannot be kept.

A medical product must not promise more than it can deliver. Persistence and adherence is of utmost importance in the context of compliant use. The product should not try to hide any negative aspects of the therapy or service it provides, or user trust may be affected.

7 GOOD DESIGN IS LONG-LASTING

It avoids being fashionable and therefore never appears antiquated. Unlike fashionable design, it lasts many years — even in today's throwaway society.

Medical products cannot adhere to latest fashions and trends because the time to market is too long and the cost to update is often prohibitive. Colours, features and details which are likely to 'age' should be carefully justified and limited to parts of the device which are easiest to update, such as labelling, graphics, packaging and GUI.

8 GOOD DESIGN IS THOROUGH DOWN TO THE LAST DETAIL

Nothing must be arbitrary or left to chance. Care and accuracy in the design process show respect towards the user.

Medical product design starts and ends with the user. Users need to feel confident before, during and after use, and quality and attention to detail will help encourage this confidence. A rigorous design process should be adopted to ensure only real needs are addressed – time should be spent perfecting the minimum number of features and interactions.

9 GOOD DESIGN IS ENVIRONMENTALLY-FRIENDLY

Design makes an important contribution to the preservation of the environment. It conserves resources and minimises physical and visual pollution throughout the lifecycle of the product.

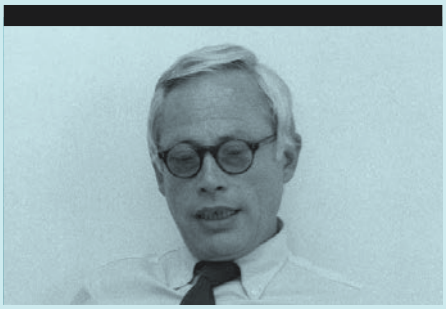
As recyclability is often not possible in the medical sector, consideration should be given to the overall impact of a product, and the material and manufacturing processes used to produce it. Can the architecture support partial reuse, for example, or can the simplicity of a design reduce the amount of material used?

10 GOOD DESIGN IS AS LITTLE DESIGN AS POSSIBLE

Less, but better — because it concentrates on the essential aspects, and the products are not burdened with non-essentials. Back to purity, back to simplicity.

We should strive for simplicity and elegance in all aspects of medical product design where every feature and function must be justified. If they are not essential to improving usability, appeal or robustness they should be removed. We should not attempt to dress products by adding superficial aesthetic details. The products we create should not feel 'over designed'.

I'm not going to claim that our design approach is revolutionary, in fact it's fairly obvious that we're following in the footsteps of great designers whose work we respect and whose approach to design we feel is appropriate to medical product development. But medical product design is a bit different, and we can't pretend otherwise. Over the years, we've had to develop our own ways of doing things to ensure our approach is relevant in an industry where a great deal of emphasis is put on safety and risk — an industry where we have to justify and validate every design decision that we make.



→ Who is Dieter Rams?
Dieter Rams is a highly influential German industrial designer who is famed for his functionalist approach to design and his celebrated career as Chief of Design at electronic devices manufacturer Braun.

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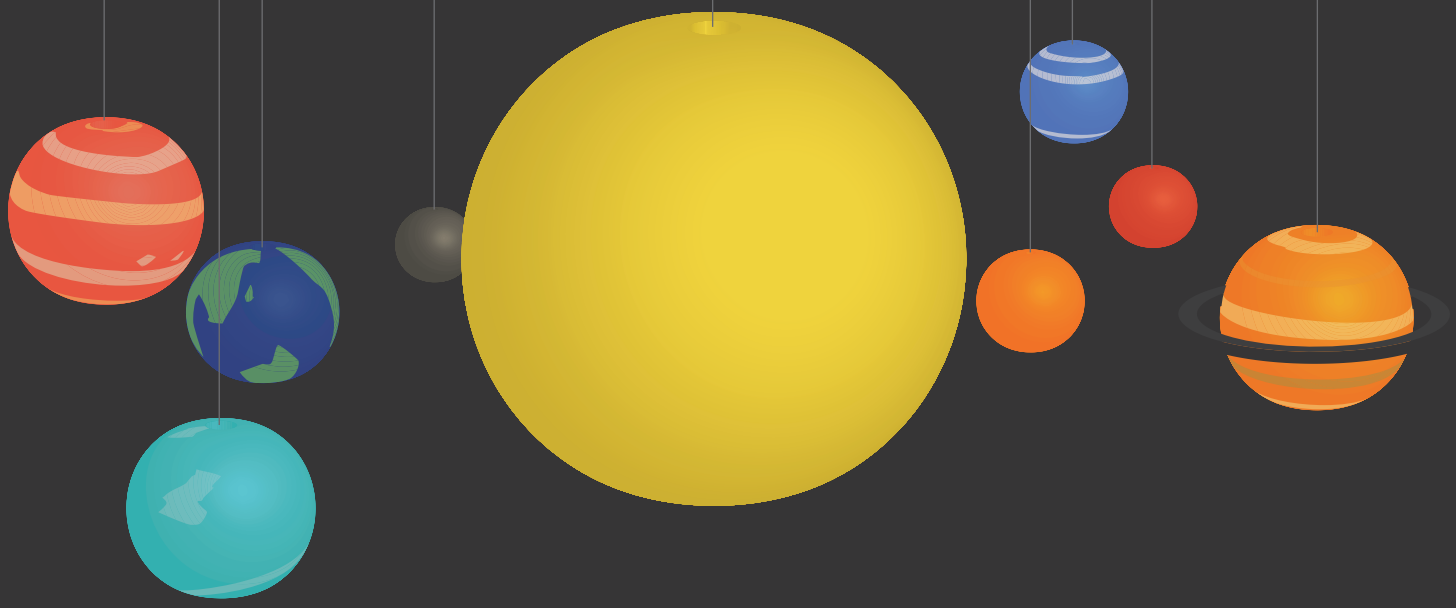
As Director of Design, Paul is a passionate advocate of the importance of 'good design' and is involved in all stages of product development from front end innovation to detailed design for manufacture.



From big bang to profitable business **the expanding universe of a medical device**

BY **AMY ROOME** AND **CHRIS HURLSTONE**

The UK has a good record of introducing new medical devices based on innovative technologies and is home to more small medical device companies than any other European country[1].

Although a number of global organisations are based here, the UK medical device industry is comprised primarily of small specialist companies, often developing single product ranges. In 2008, Eucomed estimated that there were approximately 11,000 medical device companies in Europe; more than 80 per cent of these were Small and Medium Sized Enterprises (SMEs), of which over 2,000 were registered in the UK. Yet for all the small companies who achieve commercial success, many do not. So what barriers stand in the way of expansion from seed idea to successful and profitable market launch, and how do medical device companies overcome them?

PROFITABILITY AND CONTINUED EXPANSION

A key success factor is a commercially viable product, supported by an effective sales, marketing and distribution strategy designed to achieve penetration into, and growth within, a target market.

In order to achieve prolonged sustainability, SMEs also need to plan beyond any initial financial success. Anticipation of change — and response to it — is crucial, especially in an industry dominated by high levels of technical innovation and a constantly developing regulatory landscape.

For many organisations, however, the next product enhancement or new development may not be of immediate concern. The period of time immediately following the launch of the first device is usually one of consolidation, debt repayment, and a steady progression towards overall profitability. The business plan should anticipate this transitional stage in order to avoid a number of potential failings, including:

- over-optimistic estimates of market penetration
- inaccurate predictions of manufacturing and distribution costs
- unrealistic timescales or inadequate levels of financing.

One common area where business plans can go wrong, especially if the understanding of the medical device industry is limited, concerns the costs and timelines relating to regulatory approval.

IN 2008, EUCOMED ESTIMATED THAT THERE WERE APPROXIMATELY 11,000 MEDICAL DEVICE COMPANIES IN EUROPE

REGULATORY APPROVAL AND CLINICAL TRIAL

Obtaining and maintaining regulatory approval is a business imperative as without it there is no business. And although the path to approval is highly dependent on device type and classification, it invariably requires significant effort to deliver the right technical documentation, manufacturing controls, risk management and human factors engineering. Many medical devices will also need a clinical trial, and this can often be the largest single barrier between a device and its appearance on the market.

Clinical trials can be extremely expensive and time consuming to organise, carry out, and report, and the impact of failure on a small company is potentially catastrophic. Having to postpone a trial, due to delays in the design verification phase for example, can be extremely damaging, and having to repeat the trial for any reason could bring a halt to a development programme in its final stage.

Understanding the different potential regulatory pathways for a medical device is therefore vital for success, and many SME failures result from insufficient knowledge of how to commercialise technology and how to execute the most appropriate route to market[2].

PRE-LAUNCH GROWTH

The period leading up to product launch is frequently characterised by rapid corporate growth and activities including:

Device development and design verification: The device technology at the heart of the company will need developing to the point of design verification, requiring expertise across a range of disciplines including engineering, industrial design, and human factors, plus programme and risk management. Depending on the growth model, this expertise must be recruited or bought in as an external resource.

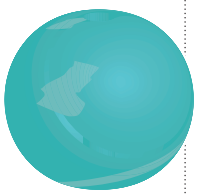
Establishing operational systems: The necessary development of a quality system and procedures, regulatory and quality assurance functions, and business development capabilities also requires the right expertise. Relying on technical staff to take on roles to which they are ill-suited should be avoided.

Manufacturing scale-up: Devices supplied to clinical trials will need to be manufactured using production systems representative of those to be used for the launch product. This scaling of prototype manufacturing lines frequently presents issues and exposes gaps in a company's understanding of the device design envelope.

At this stage, there is a risk that companies lose the broad perspective required for long-term success as they focus on developing the infrastructure and capability required for clinical trials, often with only limited resources. Millward and Lewis (2005)[3] reviewed case-studies of small UK manufacturing companies and found that such resource-constrained environments led to owner/managers focusing on short-term issues, often resulting in effects such as:

- development handicapped from the outset by unrealistic expectations
- decision-making hijacked by short-term considerations
- quality improvement activities, such as iteration and evaluation of alternatives, considered unnecessary
- quality compromised, and key development stages, such as market research, omitted.

THE COMMERCIAL VIABILITY OF THE PROPOSAL WILL BE CHALLENGED JUST AS STRONGLY AS THE TECHNICAL FEASIBILITY



This research covered new product development in SMEs as opposed to newly formed device manufacturers, but the findings are applicable in both fields. A balance is therefore required to ensure companies focus attention and effort on both short and long-term objectives.

FINANCING

Most entrepreneurs typically start out raising a small amount of money to prove the feasibility of the product idea, and then raise more over time through various routes including Government grants, venture capital (VC), banks, angel investors, investment banks, corporations and customers. Typical fundraising stages include seed, start-up, expansion and mezzanine[4] but this depends to some extent on the device technology in question.

To attract the significant funding required during pre-launch expansion, it is often necessary to develop the technology into a fully functional prototype. The amount of seed funding necessary to get to this stage will differ for, say, a novel device technology compared with larger more complex systems.

Charles Potter, founder and ex-CEO of Glide and inventor of their needle-free drug delivery system, experienced some difficulties in overcoming this funding gap: "In Europe there is a tendency to make smaller investments and link further investment to good progress. There are fewer VCs in Europe now compared with five years ago and although it is possible to secure angel funding this is often not so suitable for biotech or medtech companies where larger cash sums are required. VCs frequently prefer to syndicate to share the risk, rather than backing something they really believe in by themselves, and they often like to invest in stages, and later rather than sooner; it is

normally the last investor in a company that gets the best return!"

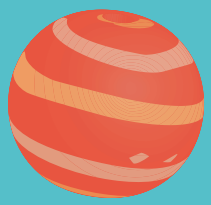
When developing a new medical device in the drug delivery sector, alternative funding can come from a collaboration with a pharmaceutical company, as they are continually looking for improved ways to deliver existing or new formulations. Negotiation of such deals can be difficult, though, as Matthew Young, founder of Oval Medical and inventor of the injector technology on which it is based, comments: "The difference in size between a start-up and its customers can be huge, and it is sometimes difficult for either side to empathise with the other. The kind of people who thrive in large institutional organisations tend to be different from those who thrive in start-ups. Culture and character type are very different."

Whether the negotiations are with pharmaceutical companies or VCs, having a clear and accurate picture of the level of funding required is an imperative, as is having a robust and effective demonstrator of the core device technology.

DEMONSTRATION OF FEASIBILITY

The extent to which feasibility must be demonstrated in order to secure funding will depend on many things including the level of finance required, the innovation management skills that you can convey, and the technology in question. The commercial viability of the proposal will be challenged just as strongly as the technical feasibility, as will the strength and capability of the management team in charge of the company. As Charles Potter puts it: "It is about management, management, management. There are plenty of mediocre ideas that have succeeded due to good management, just as there are fantastic ideas that, saddled with poor management, have failed to make it to market successfully."

For a device-based company, even the best management team must be able to demonstrate that the core technology is viable; investors always want to 'see something working'. As a result, it is sometimes easier to develop a variant of an existing – and hence proven – technology, rather than a totally novel 'disruptive' technology which can be seen as carrying more inherent risk. In this respect, close competition can be a good thing, though it is important to be able to demonstrate freedom to operate and, ideally, to achieve some level of protection for the idea.



PROTECTING THE IDEA

Some technology businesses protect an idea with secrecy, while others decide to stay ahead of the competition through speed to market and/or the quality of their products, however most rely on patents – sometimes combined with Trademark and Design Right – to defend their market position.

Decisions around IP strategy are made very early in the life of a technology company, and often represent one of the first challenges that an inventor faces. Mistakes include divulging too much before filing, or not appreciating the full scope of the invention, resulting in filings that are too narrow. Limiting the regions covered, usually in order to preserve an equally limited budget, can also greatly reduce the potential value of a technology innovation. And all this can happen before the device has even been fully realised.

THE BIG BANG…

But the biggest barrier to developing and commercialising a new idea is being able to have the right idea in the first place. From that moment of inspiration onwards, it is possible to identify the robust approaches and processes which give the best chance of success. But just as we might now know what happened one trillionth of a second after the big bang, yet not what caused it, it is very difficult to plan for that moment of inspiration (which is another challenge altogether).

REFERENCES

1 Eucomed European Trade Association for Medical Technologies Industry, 2008.

2 Quotec, Commercialising Medical Devices, 2010.

3 Millward, H, Lewis, A, Barriers to successful new product development within small manufacturing companies, Journal of Small Business and Enterprise Development, 12(3), pp379-394, 2005.

4 Bottorff, L, Funding a medical device start-Up, Medical Device and Diagnostic Industry Magazine, 2000.

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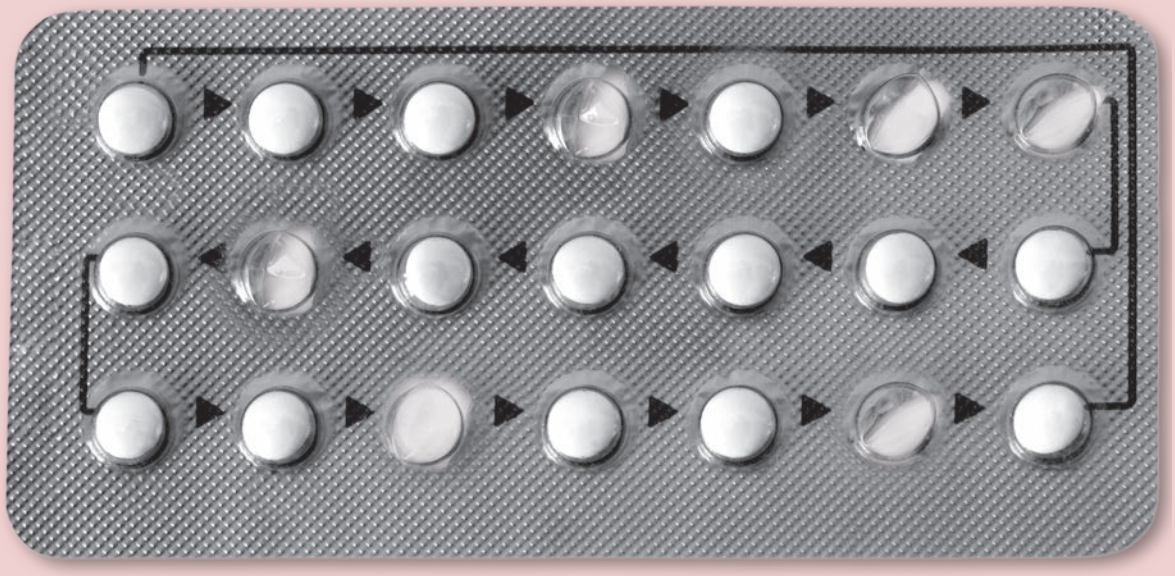


BY **THOMAS GRANT**

Medication Adherence
A Short Literature Study on Design Interventions

MEDICATION ADHERENCE IS A COMPLEX AND MULTI-VARIABLE ISSUE THAT REQUIRES A BREADTH OF UNDERSTANDING IF CIRCUMSTANCES ARE TO BE IMPROVED.

What is medication adherence?

Medication adherence is recognised as the extent to which a patient's behaviour coincides with medical or health advice[1]. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) defines medication compliance, a synonym of adherence, as 'the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen'[2].

One could interpret this as simply following 'doctor's orders'. However, medication adherence is a complex and multi-variable issue that requires a breadth of understanding if circumstances are to be improved. According to the UK's National Institute for Health and Care Excellence (NICE), approximately one third to a half of all medicines prescribed for long-term conditions are not taken as recommended[3]. Similarly, the World Health Organisation (WHO) reports that adherence to long-term therapy for chronic illnesses in developed countries averages 50% with even lower figures expected in developing countries[4].

What factors affect adherence behaviour?

There are, as one might expect, a wide array of recognised factors that impact on adherence behaviour. While a comprehensive list of recognised adherence barriers possibly extends into the hundreds, there are recurring themes that are seen across various patient groups[5]. The WHO reports five different interacting factors and interventions that affect medication adherence including[4]:

- social and economic (e.g. poor socioeconomic status, illiteracy or unemployment)
- health system/health care team related (e.g. poor medication distribution systems, inadequate or non-existent reimbursement or a lack of feedback on performance)
- therapeutic (e.g. complexity of medical regimens, duration of treatments or the immediacy of beneficial effects)
- condition related (e.g. severity of symptoms, rates of progression or level of disability)
- patient related (e.g. knowledge and beliefs, motivations to manage or confidence)

According to the Aston Medication Adherence Study (AMAS), the majority of factors affecting adherence are focused on social/economic and therapy-related factors[6]. The report suggests that age and socioeconomic deprivation are significant, albeit complex, contributors to non-adherence, with younger and older age groups showing lower rates of adherence than the middle aged.

Therapy-related factors described in the AMAS study referred to the choice of agents, the number of regular medicines taken and the complexity of the dosing regimen[6]. According to the study there was consistent evidence to demonstrate an 'inverse correlation between the number of daily doses prescribed and adherence rates'[6].

I believe that defining both the nature of non-adherence, and understanding the 'perceptual factors' that influence a patient's motivation to adhere to prescribed advice, is crucial in the design and development of medical devices.

What is the impact of non-adherence?

The consequences of low and non-adherence have widespread implications for patients, the healthcare system and society holistically. In fact, according to the WHO, there are a growing number of studies that claim that 'increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments'[4].

Poor adherence to medication regimens inhibits the benefits of medicines; this leads to a lack of health improvements for patients or, worse, a deterioration in health. Conversely, good adherence has been shown to lead to improvements in health and economic outcomes. In a

THE COMPLEXITY OF MEDICATION ADHERENCE REQUIRES AN EMPATHIC UNDERSTANDING OF PATIENT NEEDS, EXPECTATIONS AND LIFESTYLES.

study of 137,277 patients aged under 65, high levels of medication adherence were associated with lower disease related medical costs in patients with diabetes and hypercholesterolemia[7]. According to Sokol et al, the higher costs incurred by achieving good adherence are more than offset by the related reductions in medical and overall healthcare costs[7]. It has been estimated that the total cost to the US healthcare system of non-adherence is close to $300 billion annually in direct and indirect costs[8].

The consequences of non-adherence also extend beyond initial loss of sales, representing longer term issues for pharmaceutical companies. The impact upon 'brand equity' through detrimental perceptions of medication inefficacy are difficult to measure, but the implications can be significant, and are compounded by the fact that acquisition of new patients is significantly more expensive than the retention of existing patients.

Current NICE guidance refers to two different, but overlapping, types of non-adherence behaviour: 'intentional' and 'unintentional'[3].

1 Intentional non-adherence refers to a patient's decision to not follow treatment recommendations. This can include deliberately omitting prescriber advice, skipping or altering a dose or ceasing to take medication due to experienced side-effects.

2 Unintentional non-adherence occurs when the patient is prevented by specific barriers that are outside patient control. These may include failing to comprehend or understand instructions for use, an inability to pay for treatment, or simply forgetting to take medication.

The diversity and complexity of issues associated with medication non-adherence have long been researched and are well documented throughout the literature. In light of this, this article is focused specifically on how device design can influence patient behaviour and potentially lead to improved medication adherence and longer term health outcomes.

What are the possible design interventions and is there any evidence to suggest improved adherence?

Interventions to improve medication adherence for short and long term conditions can range from simpler instruction design to complex combination strategies. It should be said that many of the recognised approaches for improving medication adherence fall outside the scope of device design and development per se (e.g. pharmacist led interventions, counselling and close follow-ups). This does not mean to say that device design cannot influence a patient's adherence behaviour. To the contrary, there is a growing body of evidence to suggest that certain design related interventions can offer enhancements in adherence:

Changing the delivery route

The influence of delivery route can have a profound impact upon treatment satisfaction and consequently adherence rates. In an observational study comparing subcutaneous and oral treatments for iron chelation therapy, patient satisfaction was found to be greater in those receiving oral treatment and was typically associated with less treatment burden[9]. Rofail et al concluded that slow subcutaneous infusion negatively impacted upon treatment satisfaction which was shown to be a determinant of adherence[9].

In another study of three treatments for patients with Rheumatoid Arthritis (RA), Hetland et al found that improvements in adherence ranged from 11–15% when patients were treated with Adalimumab (52%) or Etanercept (56%) as opposed to Infliximab (41%), which supports the theory that selecting the right delivery route for specific patient populations can influence adherence behaviour[10].

Fixed-dose combinations (FDCs)

FDCs refer to switching patients from individual agents to a combined single dose regimen. This form of dosing simplification has been shown to improve adherence rates in antidiabetics, lipid-lowering agents and hypertension medication[6]. In another study, conducted by Dezii, it was reported that patients prescribed with FDCs of Angiotensin-Converting Enzyme Inhibitors (ACEIs) and Hydrochlorothiazide (HCTZ) were 20% more likely to persist with therapy for one year than patients taking equivalent agents individually[11].

Packaging design

Medication packaging has been shown to affect adherence rates. In a randomised controlled trial of 85 elderly patients, Schneider et al reported that patients receiving Lisinopril for hypertension in daily dose blister packaging were more adherent to therapy than patients receiving their medication loose in bottles[12]. Previous studies have also shown unit-of-use packaging to improve adherence rates over standard or conventional packaging in patients with type 2 diabetes[13]. However, a systematic review conducted by Zedler et al states that while calendar packaging may appear 'intuitively attractive' as a single strategy, the evidence suggesting it leads to improved adherence is inconclusive due to methodological limitations in the data[14].

Patient reminder systems

Reminder systems have been widely associated with a positive influence on adherence. In a study of 110 asthma patients using Metered Dose Inhalers (MDIs), an audio-visual reminder function reportedly enhanced adherence rates by 18% over a 12 week timeframe when compared with a standard MDI device[15]. Similarly, a randomised controlled trial of 398 patients, held over a six month period, revealed a 6% increase in patient adherence to Telmisartan among newly diagnosed hypertensive patients using a reminder device[16].

Simplify the dosing regimen

In a systematic review of 20 studies of adherence of medications for chronic conditions, all studies reported enhanced adherence rates in patients using less frequently dosed medications[6]. Saini et al reported that adherence rates were 22–41% better in patients receiving once daily dosing as opposed to two or three doses per day[17]. In another review conducted by Schroeder et al, simplification of the dosing regimen for antihypertensive medication was found to increase adherence by 8–20% across seven of nine studies[18].

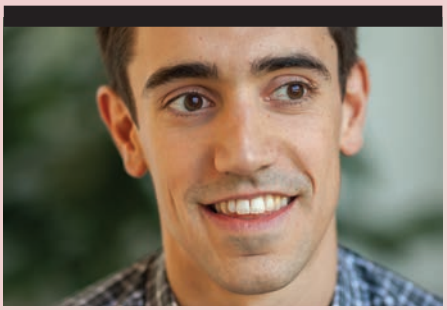
One must consider, however, that guaranteeing improved medication adherence through any single or combined strategy cannot be assured. With this in mind, I believe it is more appropriate to identify the potential problems experienced by patients in the non-adherence of a dosing regimen than to explore ways in which device design can offer improvements to such issues.

Summary

Medication non-adherence is an on-going, complex issue for the pharmaceutical industry and one that will continue into the foreseeable future. The evidence on interventions to improve medication adherence currently suggests a lack of consistently effective strategies, with no single optimal strategy recognised within the literature[4,6,19].

If improvements in medication adherence are to be made, it is believed that more emphasis must be placed upon the characteristics of patients, disease conditions and treatment regimens[1]. Realistic assessments of patient knowledge, understanding of dosing regimens, and of beliefs will then enable more effective targeting of potential adherence problems[19].

My personal view is that the complexity of medication adherence requires an empathic understanding of patient needs, expectations and lifestyles. After all, non-adherence is often regarded as a hidden problem, one that NICE states requires honest and open discussion amongst the healthcare community to develop better strategies for improvement[3]. Through collaboration with our multi-disciplinary teams, such discussions occur early in the design and development process with our clients to understand the specific difficulties that patients may experience with adherence. If the wider industry and supply chain can work closely on this topic, I believe we can enhance medication adherence through design and continuously look for new opportunities and research to build on our expertise in this area.



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Before joining Team in early 2014, Thomas was studying for his PhD in home use medical device design. His research has explored the methods and challenges for the industry in applying user-centred design principles; specifically the involvement of intended users in the design process.

WHAT DOES 'THINKING ABOUT ADHERENCE' MEAN FOR DEVICE DEVELOPERS?

BY **JULIAN DIXON, DIRECTOR OF HUMAN FACTORS**

If one thing is clear from Thomas' literature review, adherence is a complex human phenomenon. As device developers, we can't expect to be adherence experts, but we do expect to have sufficient awareness of its complexity. Awareness enables clarity of thought about what we can and should do about adherence – and about what limits our ability to influence it.

Of course, we can't have much impact on the socio-economic circumstances or age of our intended users, on the nature of their disease condition or on drug side-effects. And influencing the healthcare systems within which our products exist is a task beyond the scope of any individual company.

But working in partnership with drug and formulation development teams we can influence dosing frequency, the nature of dosage administration (e.g. IV vs SC) and, through the design of user experiences we can also influence patients' feelings about their treatment. On an increasing basis we are working with our pharmaceutical clients to improve patients' experiences often in small, but practical and significant ways, and with a focus on two basic questions:

- how can we reduce the demands we make of patients?
- how can we support patients to help them adhere?

We presented some initial thoughts on this topic at the PDA Europe Pre-Filled Syringes interest group meeting in Berlin, March 2011.

Download here
http://te-am.co/pdaeu2011

References

1 McDonald, HP, Garg, AX, Haynes, RB, Interventions to enhance patient adherence to medication prescriptions: scientific review, JAMA: the Journal of the American Medical Association 2002, 288(22), pp2868–2879.

2 Cramer, JA, Roy, A, Burrell, A, Fairchild, CJ, Fuldeore, MJ, Ollendorf, DA, Wong, PK, Medication compliance and persistence: Terminology and definitions, Value Health 2008,11, pp44–47.

3 National Institute for Health and Care Excellence (NICE), Medicines adherence: Involving patients in decisions about prescribed medicines and supporting adherence. NICE Clinical Guideline 76, January 2009.

4 World Health Organisation (WHO), Adherence to long-term therapies: Evidence for action, 2003.

5 Zeber, JE, Manias, E, Williams, AF, Hutchins, D, Udezi, WA, Roberts, CS, Peterson, AM, A systematic literature review of psychosocial and behavioural factors associated with initial medication adherence: a report of the ISPOR medication adherence & persistence special interest group. Value in Health: the Journal of the International Society for Pharmacoeconomics and Outcomes Research, 2003, 16(5), pp891–900.

6 Langley, CA, Bush, J, Marriott, JF, Wilson, KA, Establishing the extent of patient non-adherence to prescribed medication in the Heart of Birmingham teaching Primary Care Trust (HoBtPCT), The Aston Medication Adherence Study (AMAS), Final Report, 2012.

7 Sokol, MC, McGuigan, KA, Verbrugge, RR, Epstein, RS, Impact of medication adherence on hospitalization risk and healthcare cost, Medical Care, 2005, 43(6), pp521–530.

8 New England Healthcare Institute, Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease, 2009, pp1–21.

9 Rofail, D, Abetz, L, Viala, M, Gait, C, Baladi, JF, Payne, K, Satisfaction and adherence in patients with iron overload receiving iron chelation therapy as assessed by a newly developed patient instrument, Value in Health: the Journal of the International Society for Pharmacoeconomics and Outcomes Research, 2009, 12 (1), pp109–117.

10 Hetland, ML, Christensen, IJ, Tarp, U, Dreyer, L, Hansen, A, Hansen, IT, Kollerup, G, Linde, L, Lindegaard, HM, Poulsen, UE, Schlemmer, A, Jensen, DV, Jensen, S, Hostenkamp, G, Ostergaard, M, Direct comparison of treatment responses, remission rates and drug adherence in patients with rheumatoid arthritis treated with Adalimumab, Etanercept or Infliximab, Arthritis & Rheumatism, 2010, Vol 62, No 1, pp22–32, DOI 10.1002/art.27227, American College of Rheumatology.

11 Dezii, CM, A retrospective study of persistence with single-pill combination therapy vs. concurrent two-pill therapy in patients with hypertension, Managed Care (Langhorne, Pa.) 2000, 9(9 Suppl), pp2–6.

12 Schneider, PJ, Murphy, JE, Pedersen, CA, Impact of medication packaging on adherence and treatment outcomes in older ambulatory patients, JAPhA: Journal of the American Pharmacists Association, 2008, 48, pp58–63.

13 Skaer, TL, Sclar, DA, Markowski, DJ, Won, JK, Effect of value-added utilities on prescription refill compliance and Medicaid health care expenditures — a study of patients with non-insulin-dependent diabetes mellitus, Journal of Clinical Pharmacy and Therapeutics, 1993, 18(4), pp295–299.

14 Zedler, BK, Kakad, P, Colilla, S, Murrelle, L, Shah, NR, Does packaging with a calendar feature improve adherence to self-administered medication for long-term use? A systematic review, Clinical Therapeutics, 2011, 33(1), pp62–73.

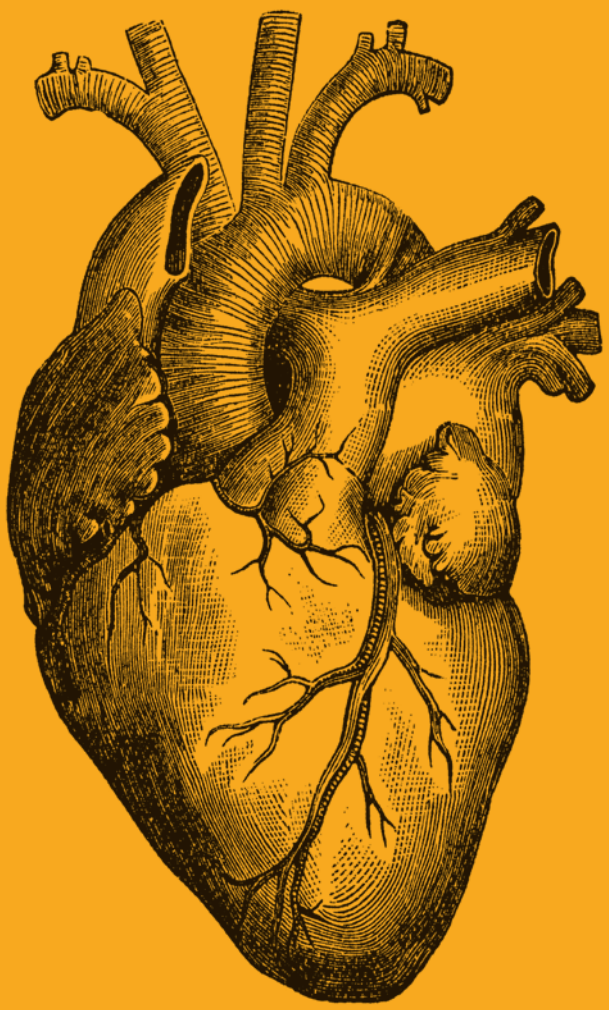
15 Charles, T, Quinn, D, Weatherall, M, Aldington, S, Beasley, R, Holt, S, An audiovisual reminder function improves adherence with inhaled corticosteroid therapy in asthma, The Journal of Allergy and Clinical Immunology, 2007, 119(4), pp811–816.

16 Christensen, A, Christrup, LL, Fabricius, PE, Chrostowska, M, Wronka, M, Narkiewicz, K, Hansen, EH, The impact of an electronic monitoring and reminder device on patient compliance with antihypertensive therapy: a randomized controlled trial, Journal of Hypertension, 2010, 28(1), pp194–200.

17 Saini, SD, Schoenfeld, P, Kaulback, K, Dubinsky, M, Effect of medication dosing frequency on adherence in chronic diseases, The American Journal of Managed Care, 2009, 15(6), ppe22–e33.

18 Schroeder, K, Fahey, T, Ebrahim, S, How can we improve adherence to blood pressure-lowering medication in ambulatory care? Systematic review of randomized controlled trials, Archives of Internal Medicine, 2004, 164(7), pp722–732.

19 Martin, LR, Williams, SL, Haskard, KB, DiMatteo, MR, 2005, The challenge of patient adherence, Therapeutics and Clinical Risk Management, 2005, 1(3), pp189–199.



A Change of Heart

BY **NICK HITCHINS**

It all started in July 1952 when Henry Opitek lay anaesthetised, breathing and alive on the operating table, yet his heart was not beating or pumping.

The Dodrill-GMR was for the first time providing mechanical assistive support by pumping blood around Henry's body. This was the first instance of an operational mechanical heart at work and it allowed Forest Dodrill, a thoracic surgeon, to perform open heart surgery on Henry's heart for 50 minutes. This innovation paved the way not only for open heart surgery but also for the development of implanted mechanical hearts.

As the development of devices to support patients during open heart surgery continued, a new question emerged: "Is it possible that a mechanical machine could replace the heart long term?" It wasn't until 1963 that this question could be answered, and the first implantable mechanical heart device was fitted to a patient who survived for four days under mechanical assisted support. This device initiated the development of Left Ventricle Assist Devices (LVADs). The key feature of an LVAD is that it supports rather

The initial expectation was that LVADs would provide long-term cardiac support for patients on the transplant list while they waited for a donor heart to become available.

than replaces the patient's heart, which continues to pump while the LVAD siphons some blood from the left ventricle and pumps it directly into the aorta. This action relieves stress on the heart, giving it a chance to recover from trauma or to repair structural damage.

The initial expectation was that LVADs would provide long-term cardiac support for patients on the transplant list while they waited for a donor heart to become available. In 1966, a device developed by the leading thoracic surgeon Michael DeBakey was used to do just that. The patient was fitted with an LVAD which supported their heart for ten days until a donor heart was found and the LVAD could be removed and the new heart transplanted.

Since then, LVAD development has moved on, and the first commercially available LVAD — the HeartMate IP LVAS — received FDA approval in 1994. It was subsequently improved and renamed the XVE, and was used extensively. This HeartMate device was an implantable pump that provided pulsatile flow (to mimic the pumping of the heart) and was driven by a pneumatic pump external to the body, and carried by the patient. These first generation devices allowed gravely ill patients to live a more normal life. You would be unlikely to see an LVAD patient running a marathon or climbing Everest, but they could live at home and leave the house for a few hours with the device running on battery power.

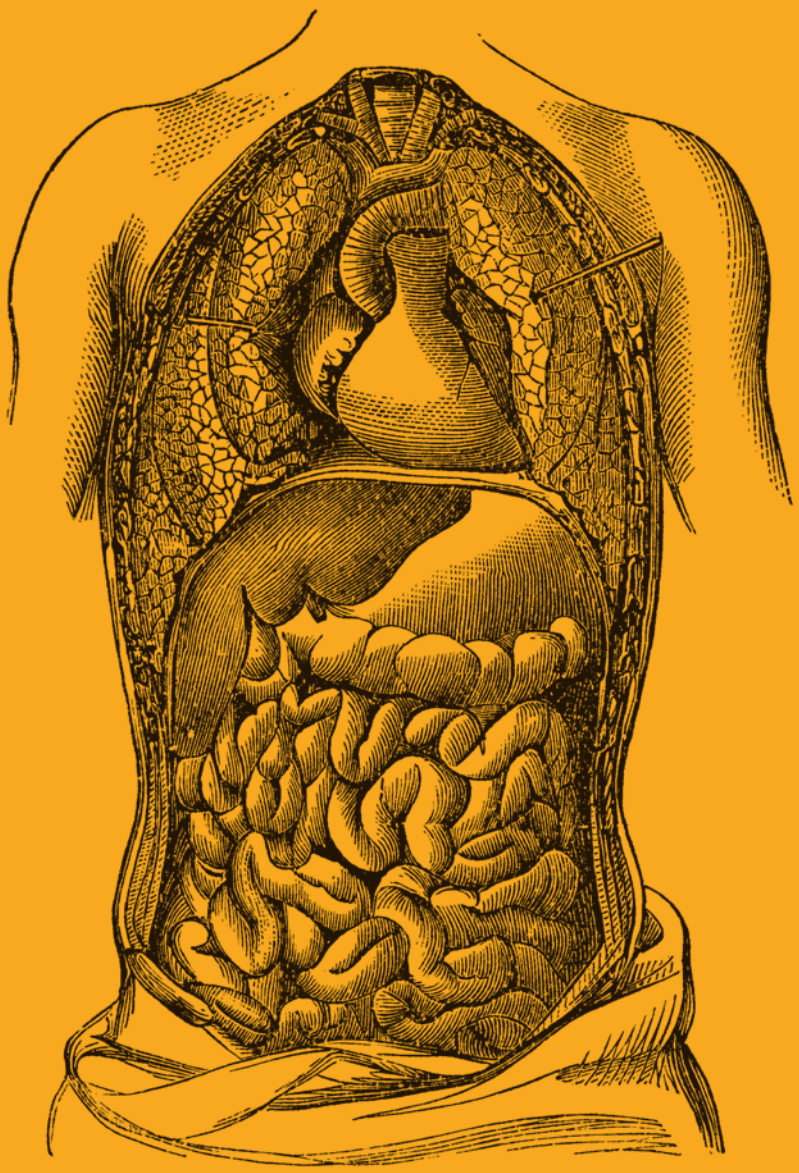
As other pulsatile flow LVADs entered the market, the number of devices implanted rose to several hundred, with some patients living with the device for up to six months before receiving a transplant. The future was looking good for the LVAD market, but there were problems; the devices were large, required heavy pneumatic pumps to operate, and they had a high number of moving parts and a large internal surface area which made them prone to failure. Clearly, more innovation was needed.

The next big step was a complete re-think, and came out of a conversation in 1984 between NASA engineer Dave Saucier and Michael DeBakey (who implanted the first LVAD). Saucier and DeBakey hit upon the concept of developing a simple LVAD based upon axial flow pumps normally used for industrial applications. With the use of NASA's engineering knowledge and supercomputers (normally reserved for modelling rocket flow) the Micromed DeBakey VAD was created and became commercially available in 1998. This new design completely changed the landscape; whilst previous LVADs were pneumatically driven pumps weighing around one kilo, and with a lifespan of a few months, this new device was driven by a tiny DC electric motor (housed within the device), weighed around 100 grams, and had a lifespan of years.

This completely new approach prompted a number of big LVAD manufacturers to go back to the drawing board, resulting in a large number of axial flow LVADs which became the second generation of the device. The most successful of these was the HeartMate II, which has been implanted into 5,000 patients worldwide. It's around the size of a D-cell battery and has a service life of five years.

Second generation devices have quickly taken over the LVAD market as their simple design and low number of moving parts have made them dependable and compact. However, they are still far from perfect and some significant problems remain, not least the high shear stresses that axial pumps place on the patient's blood. This shearing action damages red blood cells, which is not ideal for patients with a history of cardiac problems.

Since the launch of HeartMate II and similar devices, subsequent developments have been fairly incremental, such as improvements to the drive system design and the implantation operating procedure. The Circulite partial support device, for example, is sufficiently small (just larger than an AA battery) to be inserted using a minimally invasive procedure which can lead to greatly improved patient outcomes.
The market is now looking for the next innovation, and to find this we need to look away from industry developments and towards academic research. It



is here that we see some interesting ideas which focus less on changes in pumping style and more on the potential of new materials. In this promising new area, a research team at Harvard (along with other teams) has made some encouraging progress; rather than build on the existing LVAD design that syphons blood from the heart, they have decided to wrap the damaged heart in a flexible membrane and squeeze it from the outside. The design uses flexible rubber tubes encased in a membrane which, when filled with air, contracts and acts like an artificial muscle.

The Harvard design is a novel idea, embraces new materials, and is a world away from the titanium and steel LVADs currently available. Innovations such as this look set to change the landscape of the market once again, and while the road to commercial availability is a long one, it is from this area of research — in my opinion — that the next major developments will emerge. Ideas that are highly bio-inspired, and which work with the wealth of advanced materials currently in development, will lead the way in the future of cardiac support. All it needs is one manufacturer, or one start-up, to rise to the challenge and the LVAD market may be turned on its head **again.**

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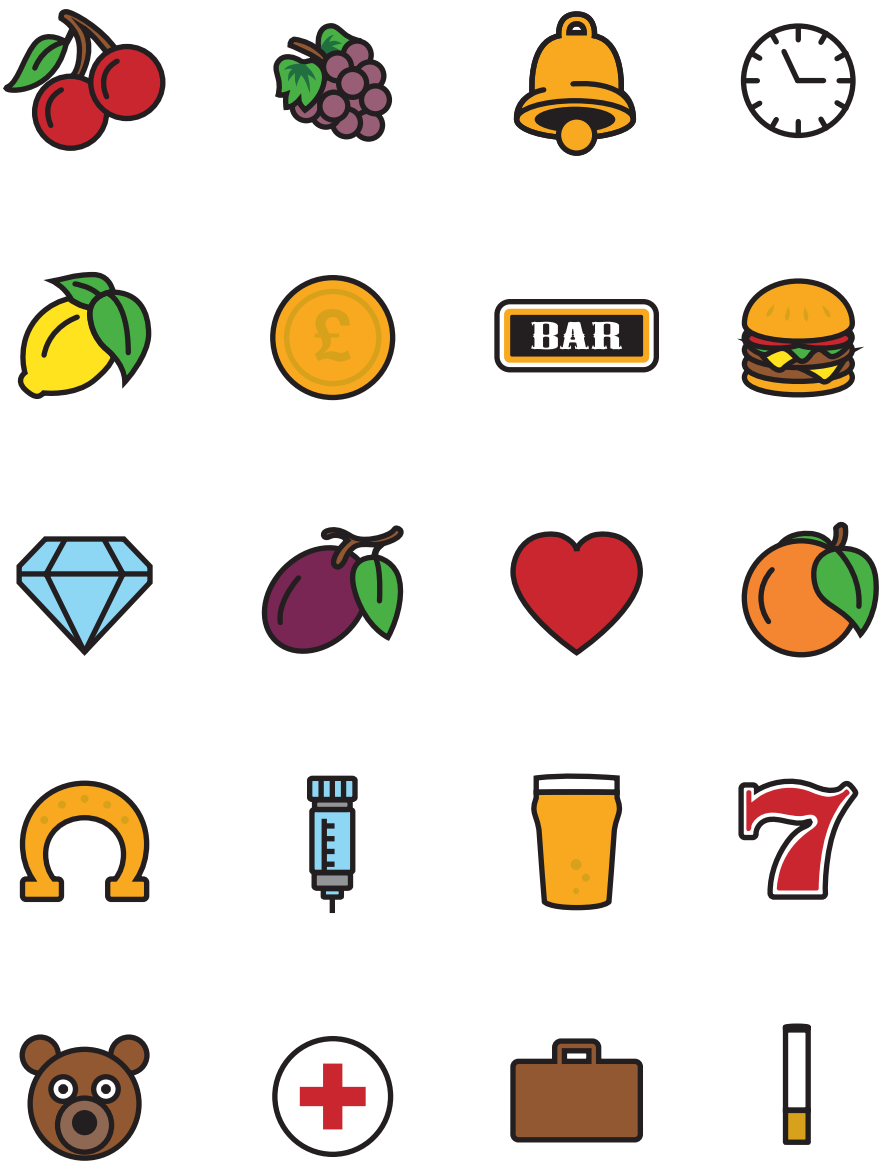
Prior to joining Team in 2013, Nick gained experience working in medical device design and development in the cardiovascular, orthopaedic and surgical areas for both commercial clients and NHS trusts.

ADHERENCE AND CARING

BY **MARTIN BONTOFT**

In the following two articles, Team's Head of Design Research looks at the lives of two patients and their personal barriers to better adherence.



Conventional wisdom states that adherence to long-term therapy for chronic illnesses in developed countries averages 50%[1]. I've also heard it said that the single most effective health improvement would be to get people to take their medicine, and I believe this to be true: the evidence looks solid and my own experience, and that of my family, tells me that it is right. But is it everything to be said?

Well, every so often, you meet someone who brings this issue into a sharp and personal focus. Peter (not his real name, but he is a real person) was diagnosed with chronic obstructive pulmonary disease (COPD) about three years ago.

This is a clever guy: he knew the effect this would have on his COPD and the rest of his body

Like many people, he was prescribed a preventer and a reliever. The preventer medicine is the UK market leader[2] which generated worldwide sales of more than $8bn[3] in 2012. It is a relatively simple, well-established therapy that most people find effective.

Peter is a clever guy, the product is proven and effective, and the NHS provides it free. So why doesn't he take it as often as he knows he should?

I met him for an internal design research project; we talked about his illness, the therapy and life in general. The diagnosis and prescription were simple; the context within which he was adhering to the therapy was anything but.

Peter doesn't blame his father for this, but he knows that growing up in a house "with a father who smoked 40 a day" is the root cause. Smoking killed his father, whose later life was blighted by the damage done to his lungs. Peter saw at first hand the physical and psychological effects of COPD and knows that, at 40, it is starting to take its toll on him. This is the emotional backdrop to his life: first-hand knowledge of the inevitable consequences of something over which he had no control.

At the same time as he was coming to terms with this diagnosis, his 82 year old mother was admitted with a serious leg infection. Over a period of time it became life-threatening; she developed septicaemia and gangrene, and eventually her leg was amputated. Peter was there for her: supporting her in the hospital, and sorting out her finances at home.

And while this was going on, Peter's wife became pregnant with their second child, a pregnancy complicated by serious bleeding at an early stage. For a while, he and his wife were unsure whether they had lost the baby.

In the background is his job. The economy is at its nadir. He is managing a team of people, trying to align and motivate them but also concerned about the many demands at home, and concerned that he is not as present in the workplace as he should be; and failure in management is a very public failure.

The culture in his business is to release the day's tensions over a beer on the way home. In the pub he forgot some of his worries for a time but, coming home, he found that his emotional reservoir was still empty. He was finding it harder to deal with life's pressures; the resilience he needed for his wife, child and family was lessened not improved, increasing his sense of failure to cope with what he believed to be the typical pressures of life.

For a while, however, the pub seemed to provide an escape but as time went on two things happened. Firstly, he came to depend on this time away; while part of him recognised that he was increasingly less present and less able to deal with all the other things in his life, for a while he was unable to do anything about it. He just got more dependent and more depressed. Secondly, his weight ballooned. At his heaviest, he reckons he was about ten stone overweight. This is a clever guy: he knew the effect this would have on his COPD and the rest of his body, he saw the result of his father's weight increase, but he could do nothing about it.

This brings us back to where we started — his adherence to the COPD therapy, which now seems the least of his worries. In fact, with everything else happening to his mind and body, it's conceivable there would have been no net benefit had he taken it twice a day.

Maybe he got so scared about where he was headed; maybe it was more positive than that — perhaps he rediscovered his sense of self-worth, that he did deserve to live better than this? Whatever it was, there was a day when Peter, alone in his office, decided to ask for help.

That was all he did, but we shouldn't underestimate the effect of that simple choice which, once made, resulted in everything a modern healthcare system has to offer being made available. Instead of struggling with this solitary burden, he is now getting real help and is recovering.

For all of us involved in the delivery of modern medicine it is sobering and yet comforting to realise that it was Peter's self-efficacy that made the difference. The professionals, the medicine and the devices were all peripheral to the transformation he made for himself. It's certainly part of healthcare's role to simply be there when the person decides to take it up again, to be accessible and usable, and to put no further barriers in the path of someone who seeks to improve their health. At their best, professionals, medicine and devices aspire to go beyond accessibility and usability, perhaps to be purposeful, attractive and collaborative. Ultimately to make people understand that good health is easily within reach and that we have a point of view: we care that they get better.

References

1 http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf

2 http://www.ic.nhs.uk/article/2021WebsiteSearch?productid=5461&q=+prescriptions+cost+analysis+2011&sort=Relevance&size=10&page=1&area=both#top

3 http://www.fiercepharma.com/special-reports/advairseretide

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I was researching the background to the design of a new drug delivery device for a drug that would have to be injected alongside insulin. My research involved meeting a lady called Mary in a McDonald's restaurant in Hackney, East London.

McDonald's was the only place she could meet, Mary said, and would it be OK if she brought her kids along? My initial thoughts were that it was going to be difficult to do a research interview in a fast food restaurant, and near impossible if she was also looking after kids. But as it didn't seem fair to say no, I just downgraded the likely value of the interview.

Well, I got there, bought the kids Happy Meals, and started to chat — and it turned out as I had feared. Her two children were always in the way. The youngest, about a year old, was on her knee and between the two of us; he needed feeding but he wanted to do it himself. He was interested in my recorder but a little envious of the attention mum was giving me. The oldest, about three, was hiding under the tables, picking up food from the floor, getting in people's way and just doing what curious three year olds do.

Mary was bouncing one child on her knee, trying to feed him while keeping the other one under control AND trying to have a conversation with me. I was getting despondent; this was turning out every bit as chaotic and unproductive as I'd imagined. In an effort to re-engage her, I described a bit of the project background: this was a drug that would have to be injected like her insulin...

"Mixed in the same pen?"
"No, in a different pen."
"But done at the same time?"
"No, it would have to be done at different times."
"But the same amount?"
"No, it might vary."
I could see in her eyes that I was losing this battle.
"Martin", she said, *"you're joking, right? How do you expect me to do that? I don't take my insulin when I should; I don't even eat when I should."*
"But you know that will make you ill, that you can get complications if you don't take your insulin?"

Mary just rolled her eyes and looked down at her kids. I looked at them too and realised the enormity of what she was saying. Her kids came first, even at the expense of her health. She knew what she was doing, but she was making a fluid choice: when she could, she'd do those things that kept her well. But her kids came first and she was OK with that compromise. It wasn't forever, but it was for now, and my second injection pen would have to wait.

She had taken a perfectly rational decision to not adhere to her doctor's prescription, and it wouldn't matter how much it was explained to her about the effect on her health, or how much we exhorted her, her behaviour was unlikely to change.

The challenge was ours: how could we design a drug delivery device that would work for people like Mary? Well, for a start it would have to recognise that her kids were more important to her than this therapy. Whatever we created, it must not get in the way or be perceived to get in the way of looking after her kids. If we did that, we would at least have achieved parity of a sort — we wouldn't have made things worse.

So, could we make things better?

These days, safety should be a given and for most of the medical devices that we encounter there are robust processes for repeated and incremental checking for potential device use error and malfunction. And this builds on the lengthy clinical procedures needed to ensure the safety, tolerability and efficacy of the drug or therapy. Bad things can still happen and we need good post-market surveillance systems to get early sight of potential issues.

Safety is massively important but Mary would probably be surprised to hear us talk about it in anything but an unqualified sense: this is a must-have, a "ticket to the game". Mary should take it for granted. We will not encourage her to use an insulin pen by simply saying it's safe or even by making sure it is.

There are health consequences for all of us if we don't eat well; Mary knows this, but it's not the most important thing right now. In this context, the effectiveness of insulin and the pen used to deliver it is not going to persuade her to use it. Although she knows diabetes management is important, for her, a regular dose of insulin doesn't make her feel noticeably different, nor does she notice the moderate fluctuations in blood glucose levels as these are largely

asymptomatic. The serious consequences of poor blood glucose control are mostly in the long-term. There is very little about the effectiveness of the device and drug that will be immediately persuasive to Mary, that will help her to prioritise it amid the other demands on her energies.

By paying attention to usability we will reduce the barriers to use; we can make the pen portable, reusable, the needle as thin as possible. We can improve other aspects of the system that perhaps make

Her kids came first, even at the expense of her health. She knew what she was doing, but she was making a fluid choice

it not quite as easy to use as it should be, such as testing blood glucose, determining the correct dose, and so on.

We could even increase the 'drivers to use' if we make the device simple, light and easy or, by taking these drivers seriously, take a much more direct approach and think of ways that use could be fun.

"Fun" seems an odd word in the context of an injectable therapy, but what we really mean is (as psychologists say) "intrinsic motivation". Something fun, that brings enjoyment, surprise, or challenge arising out of the activity itself, rather than something you are motivated to do because you want the outcome of the activity, which would be an extrinsic motivation.

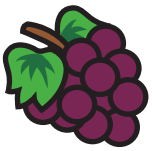
Too often we assume that people like Mary will find all the motivation they need in the rather vague (and extrinsic) notion

of 'future good health'. But that's clearly not happening, and even with her ad-hoc and haphazard approach to food and insulin Mary is feeling OK right now... so no intrinsic motivation there either.

There are lots of extrinsic motivators available to her. She knows (and is motivated by the knowledge) that one day she may not feel so well, and may rue those missed opportunities for better control. Her doctor, her friends, and her partner probably all encourage her to comply. She sees the articles and the training material available to diabetics, all of which is great, but it's all extrinsic.

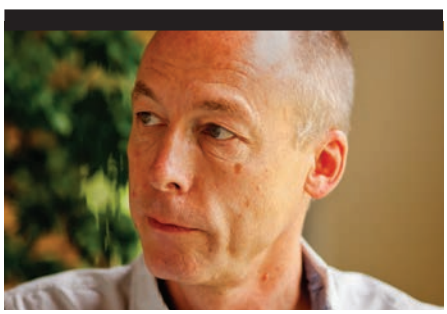
We know that intrinsic motivators are generally far more powerful, so where are they? They are there, if we look. In her handbag, she carries all sorts of things she uses rarely but keeps with her because they look nice, or they feel good in the hand, or because she feels they make her look smarter or prettier. Used as principles for the design of the device, none of these will be the silver bullet that transforms her into a model user, but each will incrementally raise the profile of that device.

What else is she intrinsically motivated by? Right now we'd have to acknowledge that being a good mum is top, so can we borrow that motivation? Is there a way we can tie better blood glucose management to being a better mum? Can we involve the kids? Could they remind her, be involved;



could it be part of a game, or educational? This is just the starting place for an exploration by brainstorm of the options that might exist.

There are several learnings here. Mary is not unusual and we probably all recognise her situation. They ebb and flow, the motivations we use to keep us doing the things we know we should. What will help is if we can design things that tap into more motivations — small and large, extrinsic and intrinsic. The key is not to assume that extrinsic motivation is all we need, and not to assume that intrinsic motivation, even fun, has no place in the design of therapies and medical devices.



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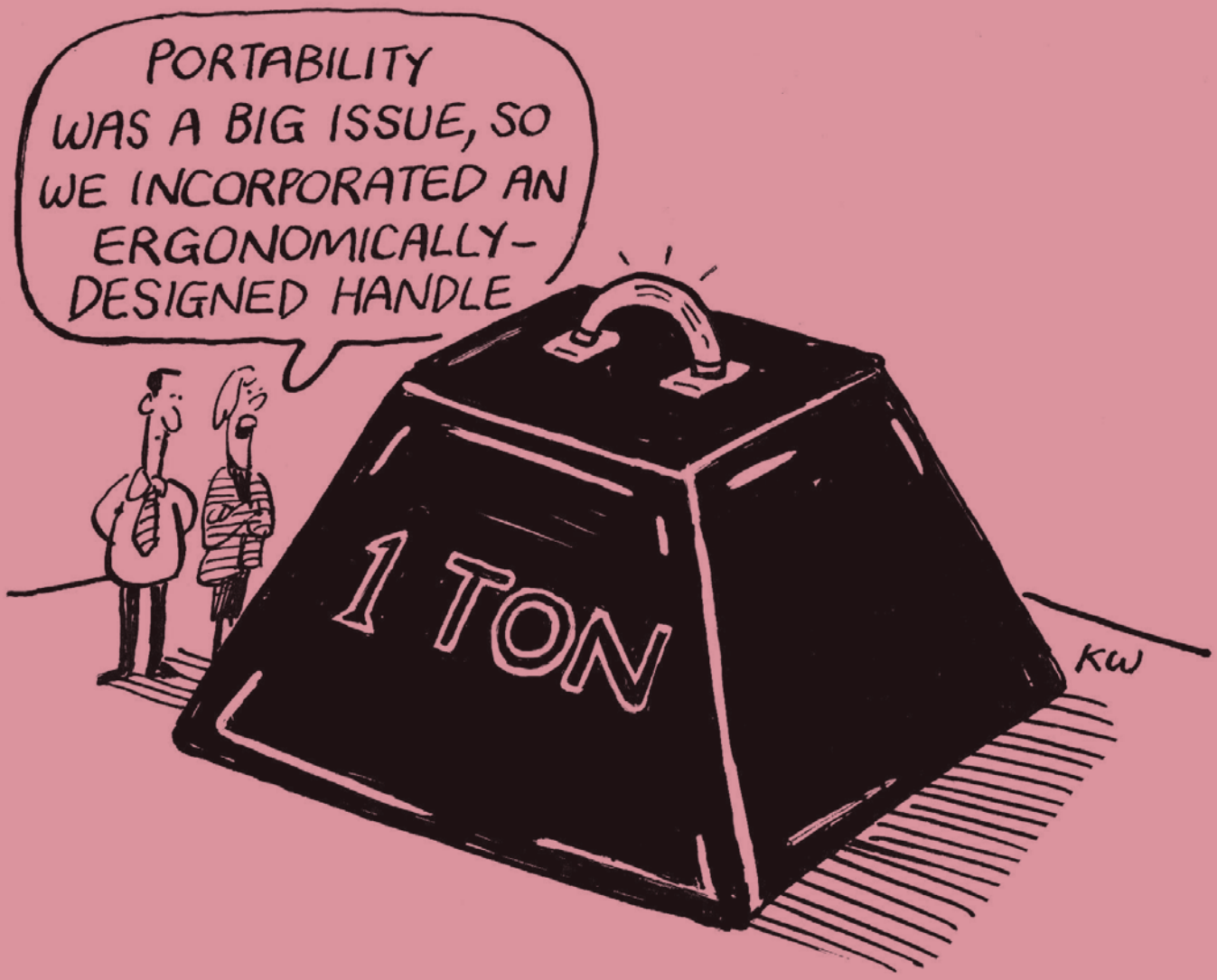
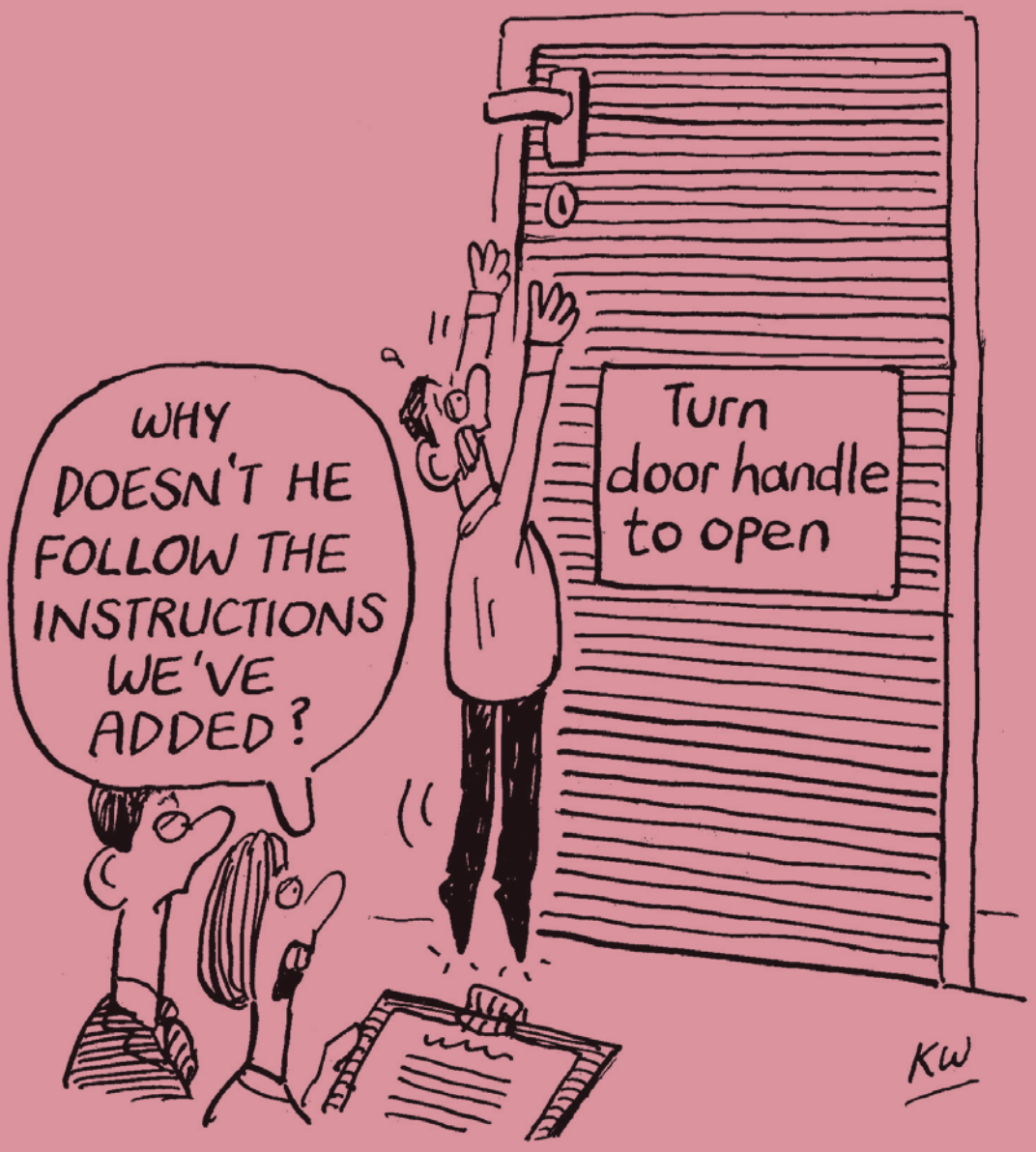
Martin heads up our design research group. He was Head of Research at IDEO for ten years before running his own consultancy and then joining Team.



Team 'toons

We recently commissioned well-known cartoonist Kipper Williams to create a series of cartoons based on our experiences and insight (as well as the experiences of our clients).

Here we highlight the importance of focusing on the right problem and not assuming that the IFU can solve everything.


WHY DOESN'T HE FOLLOW THE INSTRUCTIONS WE'VE ADDED?
Turn door handle to open
KW

Let’s make things better

We are recognised globally as experts in the design and development of medical devices. That’s all we do and we are proud of this focus. It enables us to deliver real insight and expertise to our clients.

Commercially successful products need to be safe, easy to use and ultimately make people better. Our clients like our approach, which combines design, human factors, science and engineering from inspiration right through to industrialisation.

Everybody at Team is driven by the same desire, to make things better by working in collaboration with clients and each other. Whether ‘things’ means people or the products we work on, we apply the same commitment to do the best and be the best that we can.

This focus and desire is a powerful combination and one that highlights why our clients trust us over and over again.

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