

Look, don't just see

Opportunities to innovate and improve exist. We just have to look for them

insight.
ISSUE No.4



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TAGUCHI AND THE TABLECLOTH TRICK

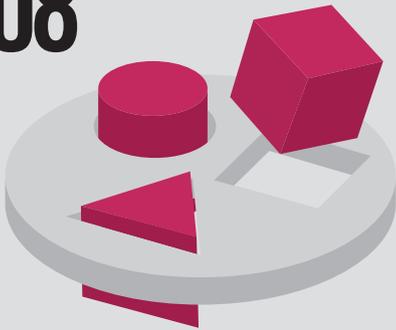
You've made it through the design process, and you are on the home stretch. Now you are transferring the device to final production tooling — and it isn't working.



SOME LIKE IT HOT

In the last edition of Insight Ben Wicks wrote about the emerging field of therapeutic hypothermia. In this issue the focus is on heat-based treatments which have the potential to cure some important diseases.

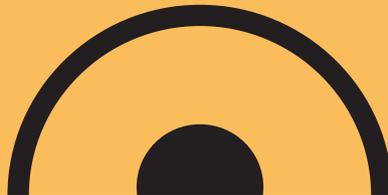
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LOOK, DON'T JUST SEE

Design research is the process we use to discover new ways to make things better... ways we can enhance people's lives and develop new business opportunities for our clients.

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What do you do when a medical device is 'running on fumes'? It is important with electronic medical devices to think about what happens when the battery power starts to fade.

Credits

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Neil Cooper / Angela Murray
Designed by: The District

Team / insight.

02 — 03

Tough stuff

BY **DAN FLICOS**

Innovation is hard work, but the rewards can be high if you get it right. Edison said: "Genius is 1% inspiration and 99% perspiration" and the same is true of innovation. To take a breakthrough idea from the lab into a successful product takes a lot of hard graft – it requires teams working together across a wide range of usability, design, engineering, regulatory, manufacturing and commercial disciplines.

This issue of Insight focuses on some of the key areas that underpin successful innovation from spotting new opportunities, to understanding users, problem solving to detailed engineering analysis. We also highlight one of the most exciting projects that we've ever worked on – the world's first normothermic liver perfusion system. You may have seen it on the news recently as it was announced that the first clinical studies had been conducted. On page 24 you can read all about it and there is a link to a really great documentary that tells the full story.

So we wish you well with your innovations – and please enjoy this latest issue of insight.

— dan.flicos@team-consulting.com
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 **team.** | medical design and development

Team / insight.



WE'VE ALL SEEN
ARTICLES AND
BLOGS ABOUT
THE CHALLENGES
OF DELIVERING
MACROMOLECULE
'BIOLOGICALS'
ANDY FRY TAKES A
LOOK AT THE HOW
AND WHY

Injecting Golden Syrup

BY ANDY FRY

It's been 60 years since Watson and Crick published 'A Structure for Deoxyribose Nucleic Acid' in the April 1953 issue of 'Nature'. Nineteen years later, in 1972, Paul Berg's team at Stanford University created the world's first recombinant DNA molecule. Wind forward to 1976 when biochemistry professor Robert Swanson shared a beer with venture capitalist Herbert Boyer in San Francisco and roughed out a business plan for the company we now know as Genentech, an event described as 'the foundation of not just a company but an entire industry'. Just six years later, in 1982, Eli Lilly launched Humulin®, the world's first human insulin produced using recombinant DNA technology, developed by Genentech working with the City of Hope Medical Research Center in Pasadena.

Since the 1990s, biologically derived drugs have been the centre of attention for the pharmaceutical world, both in terms of therapeutic opportunities and of business activity.

Global sales of biologically derived drugs are expected to exceed \$220 billion by 2015, with more than 500 monoclonal antibodies ('mAbs') currently in development.

So that's all good isn't it? After all, previously untreatable conditions are now manageable. But just like insulin, these protein-based drugs are rendered useless if taken orally, so something other than a tablet or capsule is called for. Does that present any new challenges?

Size IS important

People with diabetes have been successfully injecting themselves (daily with insulin) for over 90 years, so you might expect that self-injection of any other drug should be straightforward. However, it's not that simple; insulin, with a molecular weight of 5.8 kDa, seems a pretty chunky molecule when compared with drugs such as aspirin (at 180 Da) or even penicillin (at around 335 Da).

*People with diabetes
have been successfully
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for over 90 years*

Now consider Humira®, a hugely successful product used to treat a range of autoimmune conditions including rheumatoid arthritis, ankylosing spondylitis and Crohn's disease. It has a molecular weight of approximately **148 kDa**. Humira® is 25 times the size of the humble insulin molecule, and is anything but simple - the chemical formula provides a clue here; $C_{6428}H_{9912}N_{1694}O_{1987}S_{46}$. As a mAb, it works by binding onto specific target sites on cells; the headcount of individual mAb molecules has to be

large to address the cell targets, hence a therapeutic mAb dose comprises a large payload of bulky, complex molecules, which have to be delivered by injection.

So what are the practical options?

The cost and convenience drivers for self-administered therapies, especially for chronic conditions, result in regular but infrequent injections of relatively large payloads of molecules, injected weekly, possibly fortnightly or even quarterly. Injection of 1 ml in a single, self-administered dose has historically been regarded as the threshold of acceptability, but single injected doses of up to 2.5 ml are now being actively explored. Discomfort or pain are major

considerations, but time also forms a part of the equation; in general, patients don't want to hold an autoinjector (an increasingly common delivery device format for biological drugs) in place for more than 15 seconds, a time window which includes needle insertion as well as the actual injection.

Syringeability

This term refers to the force required to inject a given solution at a given rate via a chosen needle length and gauge. Flow through a hollow needle is characterised by the Hagen-Poiseuille equation (see page six).

Although syringe plunger friction and tissue resistance at the needle tip will add to syringe plunger force, viscous resistance within the needle is particularly relevant as larger molecules and higher mg/ml concentrations result in higher viscosity formulations. Needle gauge is key; although a finer needle means easier and less painful insertion, it also has a smaller bore. Equation 1 (overleaf) shows that plunger force varies with D^4 ; change from a 27g needle with a bore of 0.191mm to a 30g needle with a bore of 0.140mm and the plunger force increases by **350%**, if the flow rate, Q , (hence the injection duration) is to stay the same.

For a spring-powered autoinjector, the spring must provide adequate force at the end of stroke (as the last drop of drug is delivered). However the stiffness or 'rate' of a traditional coil spring dictates that at the start of delivery, the spring force will be significantly higher. Add on the syringe plunger friction and tissue resistance, plus a safety margin to allow for tolerances, and it becomes apparent that some surprisingly high forces have to be handled by the injector mechanism and, specifically, reacted through the injector's small glass syringe. Not surprisingly, breakages, failures and malfunctions are among the problems faced by autoinjectors delivering higher viscosity biologic drugs.

Responses to these challenges are being developed, including thin-walled



The needle-free DosePro from Zogenix

1: The Hagen-Poiseuille Equation

$$F = \frac{128Q\mu LA}{\pi D^4}$$

2: THE BERNOULLI EQUATION

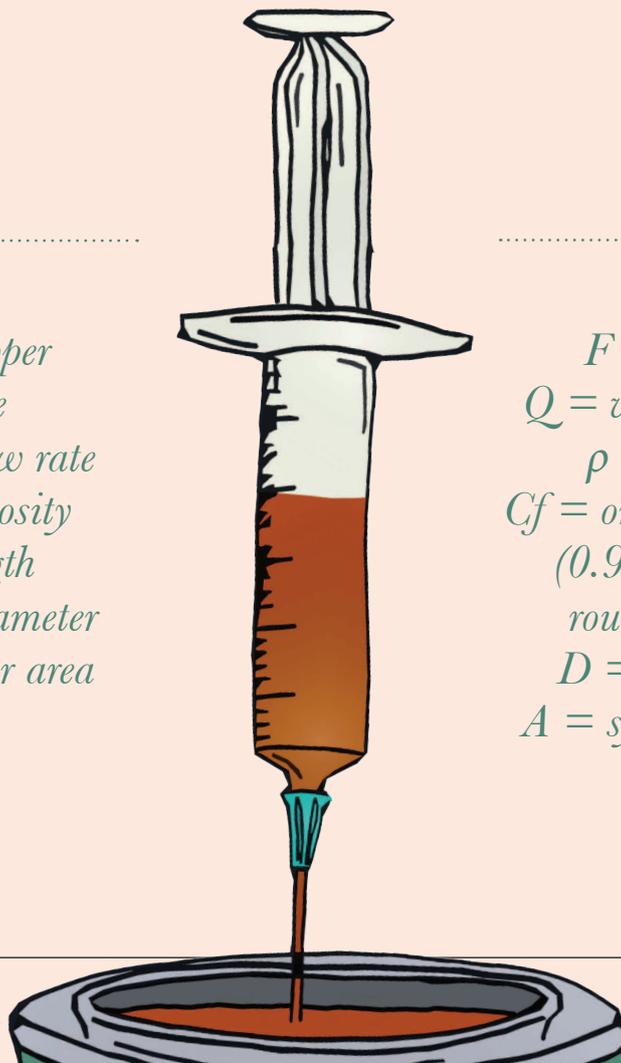
$$F = 2\rho A \left(\frac{4Q}{C_f \pi D^2} \right)^2$$

1

F = syringe stopper
(plunger) force
 Q = volumetric flow rate
 μ = dynamic viscosity
 L = needle length
 D = needle bore diameter
 A = syringe plunger area

2

F = plunger force
 Q = volumetric flow rate
 ρ = fluid density
 C_f = orifice flow coefficient
(0.95 for a practical,
round-edged orifice)
 D = orifice diameter
 A = syringe plunger area



or tapered needles to reduce viscous resistance and minimise pain; constant-force springs and dampers to minimise peak forces; precisely moulded cyclic polyolefin syringes which are more robust than glass; and reduced friction stoppers and syringes. But why not just change our approach to injected delivery and side-step some of these challenges?

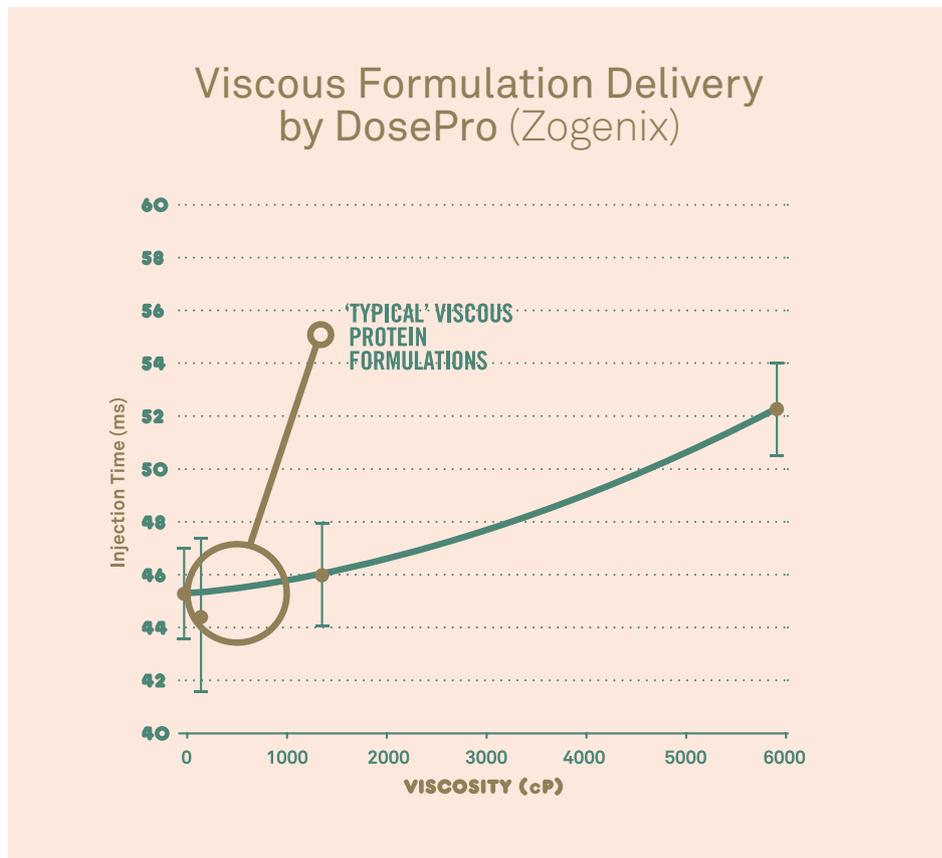
The time machine

If we treat injection time as an opportunity, not a challenge, it presents a very interesting device scenario. When applying the Hagen-Poiseuille equation for an autoinjector, the flow rate, (Q , in equation (1), of 1ml or 2ml in perhaps 10 seconds), is driven largely by the acceptable operating time for the patient. But if the injection device could be worn, say for an hour, then the flow rate for the same injection size reduces by 36,000% - and equation 1 tells us that the plunger force would reduce in the same ratio. In fact, the drug formulation could be less concentrated (and less viscous), though of larger volume, say 5ml or even 10 ml, while the flow rate and force to deliver would remain very manageable. Welcome to the LVI (large volume injector) or 'bolus delivery device'.

A number of devices of this type are in development, and use a variety of primary containers (glass, plastic, flexible, rigid, 'traditional' and novel variants), and a range of mechanisms, power sources and control systems (mechanical, electrical, electronic, hybrid). The LVI addresses some key autoinjector challenges and much effort is being devoted to the technical, pharmaceutical and user related aspects of LVI devices.

When's he going to talk about Golden Syrup?

OK, I hadn't forgotten. Golden Syrup (or Karo Syrup, if you're from the USA) is around 3000 cP and although few pharmaceutical products have viscosities this high, injection of higher viscosity products remains of interest. Needle-free delivery has been a reality since the late 1940s, and several technologies are now available.



Needle-free delivery uses a fine, high velocity jet generated by driving liquid through an orifice at high pressure in order to pierce the skin and underlying tissue. The governing equation (by Bernoulli) can be rearranged as shown (see equation 2).

Comparing this with the Hagen-Poiseuille equation (1), the only fluid property in the Bernoulli equation is ρ (density) and there is no viscosity term. Since drug formulations generally have densities close to that of water, the implication is that a needle-free device will deliver the same volume, at the same rate, using the same energy, largely irrespective of viscosity.

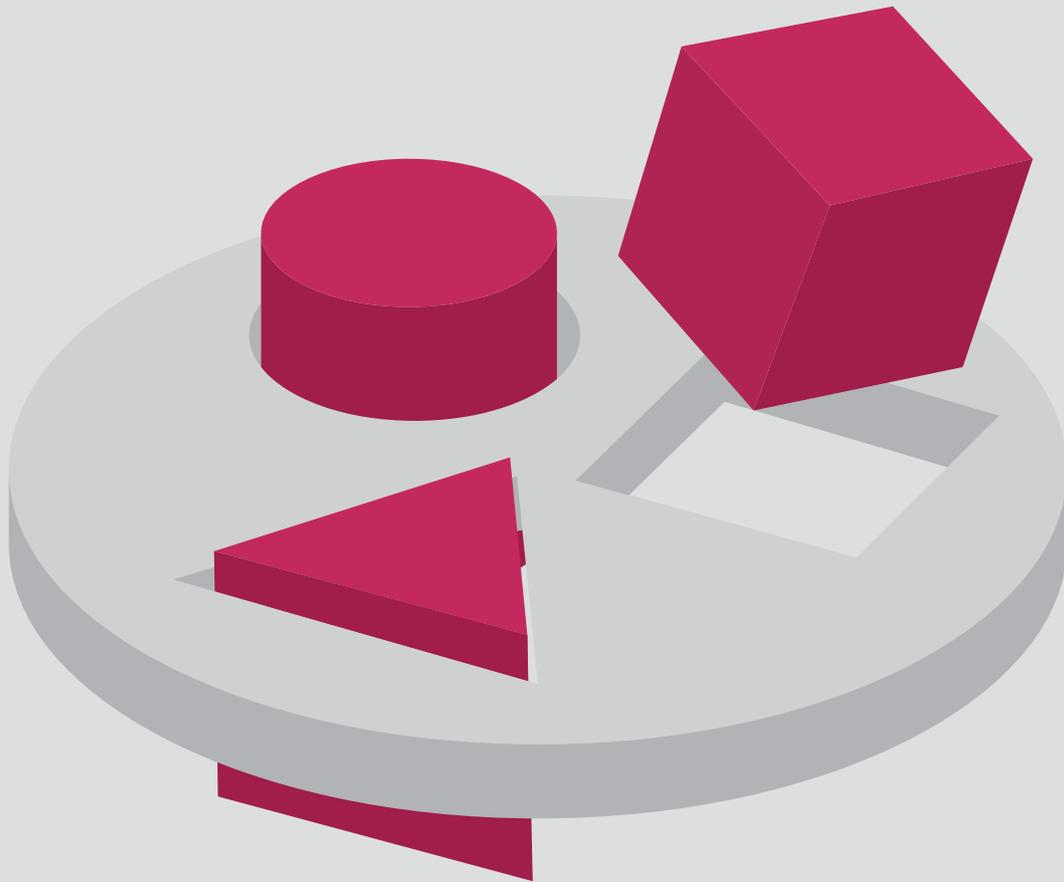
Strictly speaking, this holds true for orifice plates of zero length and hence is not the only governing relationship for a practical, real life device. Nevertheless, although practical orifices do have a finite length and do exhibit some viscous loss, needle-free devices are largely unaffected by product viscosity in the practical range of interest, as the above figure kindly provided by Zogenix illustrates.

Which to choose?

All three injection technologies discussed above have their place, but often selection is left until late in the development of the drug product. This can mean that opportunities can be missed. Early exploration of formulation options together with the increasingly wide range of real, practical, options for parenteral delivery can provide significant benefits to everyone from the Pharmaco to the patient.



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Rethinking one-size-fits-all

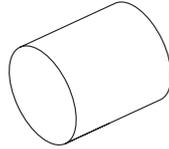
BY PAUL GREENHALGH

As medical device designers, we care greatly about patient experience. Let's face it, you don't desire an inhaler or auto-injector. They are necessary products to manage your health or even save your life, yet they evoke a number of negative emotions, such as confusion, fear and anxiety.

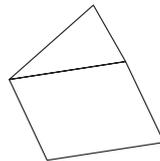
The patient experience is affected by every touch point – by the device, the instructions, the packaging, even any supportive mobile apps offering reminders - and so it is important to think holistically when designing the device to ensure that themes and messages are communicated consistently.

However, we need to go one step further and ensure that devices are targeted as closely as possible to the physical and emotional needs of target users as by doing so we increase the chance that the device will be used and used correctly. This is not the silver bullet for improved compliance but is one positive step towards this noble ambition. It is certainly a departure from the current one-size-fits-all approach which is the norm, but which does not meet the expectations of patients used to living in a world of choice where they surround themselves with products – from cars to toothbrushes - that meet their unique emotional, physical and lifestyle needs.

Although the pharmaceutical industry will never copy consumer products, there is a middle ground to aim for where safety and efficacy are proven but where patients also have a number of options which, by meeting their 'lifestyle' needs, improve their compliance with the device they are given. After all, the device isn't 'just packaging', it is the interface between the drug and the patient.



THE DEVICE ISN'T 'JUST PACKAGING', IT IS THE INTERFACE BETWEEN THE DRUG AND THE PATIENT



COMPLIANCE

For some time there has been a suspected link between user satisfaction with a device and compliance with treatment regime. This has been difficult to quantify because a range of consumer styled device variants isn't commercially available.

In 2012, however, UK supermarket chain Asda started selling asthma inhalers over the counter without prescription, potentially starting the trend towards greater consumer choice. When a doctor prescribes a medication they make the decision for the patient. When the medication moves into the store, the patient makes the decision to buy based on aspects important to them, such as look and feel, brand name, features, functions, and on the opinion not only of prescribers but also of friends, peers and online communities.

MORE INFORMATION

Information is no longer restricted to what the prescriber says. It is possible to share and form opinions online and what somebody's peers say on Facebook can have considerably more impact on choice.

MORE COMPETITION

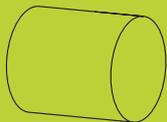
Competition between therapies, already evident, will only increase as more and more drugs and devices come off-patent. The generic players will look for opportunities for differentiation, and whilst they can't change the core device, design does provide an opportunity to gain advantage.

One of the best examples from within the medical sector is the Novopen from Novo Nordisk, which for many years has exploited the power of design to create devices with strong appeal and emotional connections, such as the Novopen Echo for children which can be personalised. The device has the same core functionality and the same device architecture but minor modifications make it more appealing to different user groups.

Patients are diverse. They have different cognitive and physical capabilities, different lifestyles, attitudes, beliefs, aspirations and preferences. Their

device requirements are affected by their age, location, who they live with, their job, leisure pursuits and, importantly, their attitude to their condition. A 12 year old girl in upstate New York is very different to a 70 year old woman living alone in a Paris suburb, yet their treatment regime may be very similar and - at the moment - the drug and device they are prescribed will be exactly the same. A further level of differentiation is added by the growing number of users in emerging economies, so the issues presented by diversity are not going to disappear.

Current drug delivery devices are a bit like Ford's original Model T - available in any colour as long as it's black. This one-size-fits-all model is not used in other successful markets and presents a commercial risk if your competitor's product has greater appeal to a significant market segment. But we are not designing kettles or toasters. In the pharmaceutical industry we don't have the luxury of making post-launch modifications and updating models every 12 months to keep up with trends. This focus on a single device exists for a good reason as the development and regulatory burden of marketing multiple variants is time-consuming and expensive. So as the industry is pushed towards greater consumer choice, what is a realistic target?



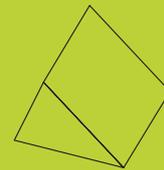
We can't ignore the regulatory hurdles. Any change that impacts on performance and you are back in the clinic. Change the user interface - even change the instructions - and you're back to human factors studies to prove that it doesn't affect performance. It is important to acknowledge these hurdles, and that they aren't simple to overcome, but there is a way of structuring the device architecture to give us maximum design freedom whilst limiting the effect on costs and timescales. Even if you are licensing-in a platform it is important to understand the potential for customisation whilst undertaking due diligence.

DRUG DELIVERY DEVICES ARE A BIT LIKE FORD'S ORIGINAL MODEL T - AVAILABLE IN ANY COLOUR AS LONG AS IT'S BLACK

WHAT DO WE MEAN BY DEVICE ARCHITECTURE?

It is possible to break a product down - in this case a drug delivery device - into layers in order to isolate each component of the design, assess design choices, and look at the combined product - the device architecture.

Firstly, start with the device core - this could be the engine, the primary drug containment, the mouthpiece and airways (if it is an inhaler), or the delivery mechanism (if it is an injector). Consider the device core as sacred. Change it at your peril! So what other options do we have?



See opposite

1. FORM FACTOR

The shape and size of the device

2. FEATURES

Such as a dose counter, compliance monitor

3. AESTHETICS

The look and feel of the device

4. IFU / IPL

The instructions or patient information leaflet

5. CARTON

The carton in which the product is supplied

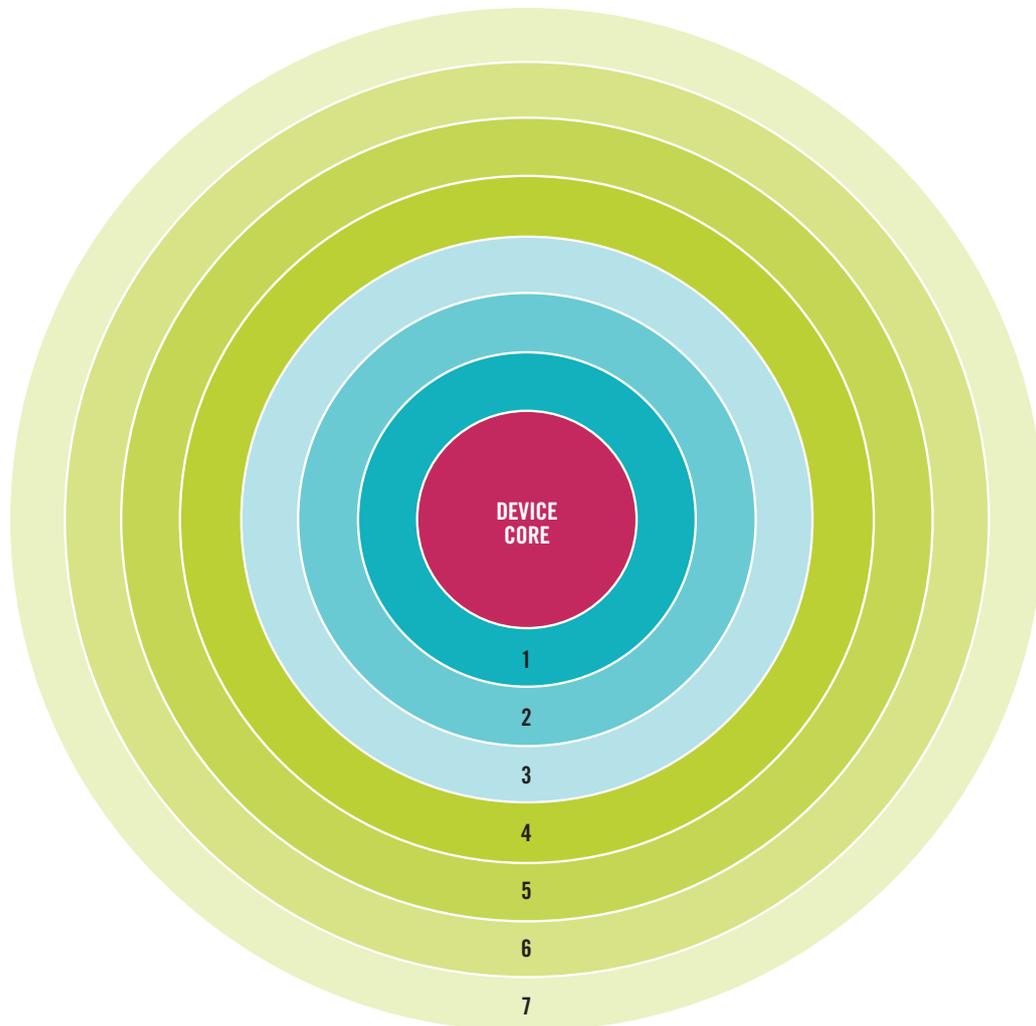
6. ACCESSORIES

Any accessories that the devices is supplied with

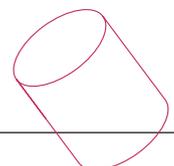
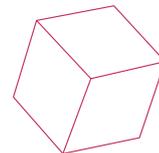
7. APPS

Any mobile applications which the device or patient interfaces with

THE DEVICE ARCHITECTURE



Each stage offers opportunities to modify the device or to personalise it. Any variation will cost time and money so we need to decide what design changes can be justified. But how do you make this decision? The answer is by introducing real users into the design process and carefully considering the impact of any change from a regulatory, commercial and technical perspective.



To demonstrate what is both possible and reasonable, let's briefly look at three inhaler users with three different design briefs.

USER A

John, a 48 year old Marketing Director. He travels a lot on business and likes to travel light. He wants convenience, recognises quality products and can afford them, but is sensitive to the environmental impact of throwing away lots of plastic. The look of his inhaler matters but probably less than the size.

**THERE ARE
COMMON
REQUIREMENTS
RELEVANT TO ALL
THESE USERS**

USER B

Tom, a 12 year old school boy with a very active lifestyle. He needs his inhaler when he is away from his parents but needs encouragement to take it correctly, and monitoring his use is a constant struggle for his parents. Tom cares what his inhaler looks like and what his friends think about it. He isn't careful with it and throws it into his sports bag. Size isn't a particular issue but robustness and personalisation are.

USER C

Mary, a 75 year old woman living in a warden controlled flat. Her inhaler is only one of a number of daily therapies. Mary gets quite confused and it is all about ease of use. Size isn't important, if anything she'd like her inhaler to be bigger, and easier to handle. She finds technology confusing but like John, she doesn't like throwing things away.

There are common requirements relevant to all these users but there are also some very specific requirements. Mary wants a larger inhaler, Tom and John both want a small and compact device, so we choose the small device as our base product. Tom needs something he can personalise, Mary and John don't, but we should consider this when developing the base product.

In this example, a common capsule inhaler is the device core.

SOLUTION A

The base product would satisfy John. The inhaler features a secondary (factory fitted) component which allows customisation for different users and includes a mouthpiece cover (a non-critical part) that can also be customised. The overall aesthetics give a feeling of quality and efficiency, whilst the form factor is compact with smoothed edges to make it pocketable. The increased length of the mouthpiece cover protects the airways and piercing buttons whilst in a pocket, and a capsule storage compartment improves convenience.

SOLUTION B

Aimed at Tom, the base component is manufactured in a rubberised material to improve robustness and integrates a compliance monitor, allowing parents to check usage. The same mouthpiece cover component is designed with a single curving surface to allow Tom to apply self-adhesive skins to personalise it.

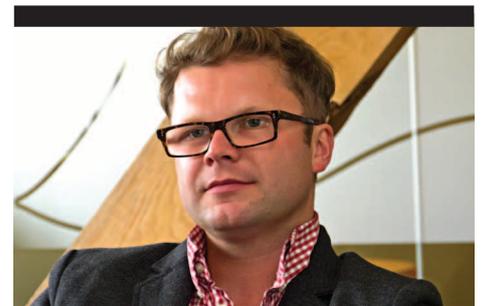
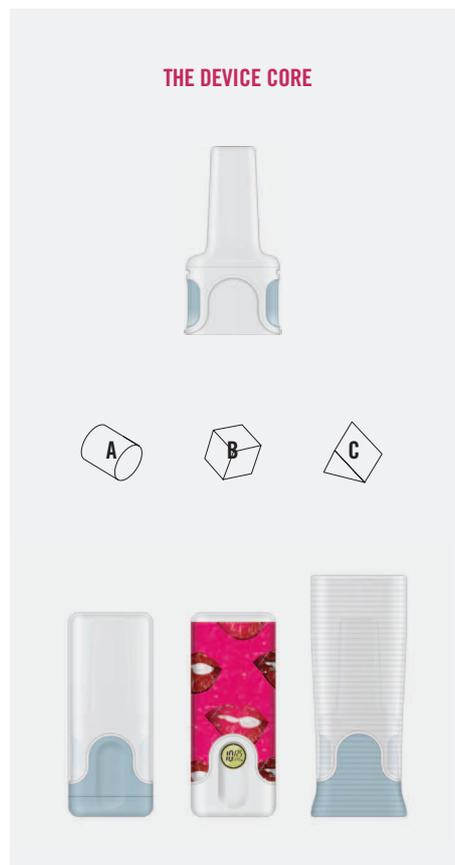
SOLUTION C

For Mary the small compact base now has a larger tapered base which allows her to hold the device firmly against a flat surface when loading. The device also has a larger tapered cap and added grip all over to improve ease of handling.

These devices are designed to meet the needs of three very different user profiles but are based closely on a 'one-size-fits-most' product with no changes to the device core.

This approach can also extend to device peripherals such as the packaging, instructions and supportive mobile apps. For Tom, for example, the packaging could use brighter colours, the box could feature a pack of self-adhesive stickers, and the instructions could be designed in a youth-orientated style and could contain other information about the device and asthma.

To date, choice has not been a concern in the pharmaceutical industry but the significant market drivers in the market around compliance, consumer choice, availability of information and increased competition mean that we need to start thinking this way. Yes, there are still regulatory burdens, and commercial barriers, but by adopting a user-centric design approach from the outset, structuring the device architecture to facilitate customisation, and considering how other product aspects can enhance the user experience, it is possible to create more appealing devices whilst working within necessary industry constraints.



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Taguchi and the tablecloth trick

BY PHILIP CANNER +
RHONA SINCLAIR

You've made it through the design process, and you are on the home stretch. Months, maybe years ago, you started with a core idea, took it through brainstorms, created various concepts and handling models, proved the principle on test rigs, tested prototypes in the lab and with users, made batches of devices on pilot tooling, and may have even done some clinical trials. Now you are transferring the device to final production tooling — and it isn't working.



Unfortunately, this scenario happens more often than one might expect. Maybe it's the change in tooling, such as an increase in cavitation; maybe because you're testing larger numbers of devices, previously unseen problems are becoming apparent; maybe it's the move from manual to automated assembly. There are probably a number of potential reasons but identifying the most likely cause - and how to address it - could determine whether the product is launched or not. And that is where a sensitivity analysis, undertaken early in the development process, could make all the difference.

A sensitivity analysis is a process for determining the magnitude of the effects that design changes have on the performance of a system, allowing you to build a robust design with knowledge of its limits. If decisions need to be made, or problems arise, during any development stage, a sensitivity analysis can help evaluate and solve these issues with minimal design change and disruption, and hopefully minimal cost. But when and how to do it?

One way is to conduct experiments: make a change, measure performance, make another change, measure performance, and so on, perhaps using Taguchi methods to optimise your experimental design. However, sometimes physical testing isn't an option - in the early stages of the development, for example, when components are not yet available, or during the later stages when making changes to production-quality tooling may be too costly, too risky, or take too long. So if you can't conduct physical experiments, what can you do?

One answer is to employ some of the "heavier" computer-simulation tools such as Finite Element Analysis (FEA) and Computational Fluid Dynamics (CFD) which, for single components or very simple mechanisms, can provide a method of conducting a sensitivity study when physical testing is not possible. However, problems are rarely limited to single components or simple interactions. For devices such as injectors or inhalers, with several moving



UNLIKE A PHYSICAL EXPERIMENT, WITH A MATHEMATICAL MODEL WE MAY BE ABLE TO CONDUCT EVERY PERMUTATION OF DESIGN CHANGE

**—
A NICE LUXURY IF WE ARE NOT SURE OF INTERACTIONS IN A SYSTEM.**



and flexing components, the limiting factor with detailed FEA (or CFD) can be the significant simulation time required - hours or even days. As a result, analysing several possible design changes simply becomes impractical.

In such cases, the solution may be to go back to basics. Using known equations of trigonometry, physics and engineering to describe the behaviour of the device in terms of input parameters (such as dimensions), and output results (such as performance characteristics), we can mathematically model the device and its behaviour. Written in software such as MathCAD or Matlab, a mathematical model often requires significantly less computational resource - and hence simulation time - than FEA or CFD, and provides a very quick way to run virtual experiments, changing design inputs and logging the performance outputs.

Unlike a physical experiment, with a mathematical model we may be able to conduct every permutation of design change - a nice luxury if we are not sure of interactions in a system. In the same way, we can use Taguchi to design a set of physical experiments to help us structure the virtual experiments and the analysis of the results, helping us make best use of time.

Speaking of time... we may have a set of individual component interaction equations describing the system as a whole, but unless we consider the related dynamics and kinematics - how interactions are dependent on time - we may miss critical aspects of performance. Consider the tablecloth trick. The force applied to the cup and saucer, via the tablecloth, is sufficient to drag them off the table. If we were to consider equilibrium, steady state conditions, we would smash the crockery every time. But if we consider the speed of movement of the cloth, we realise it has been pulled out of the way before the frictional contact forces have had a chance to accelerate the cup and saucer, which remain on the table.

So, to really understand what is going on, we must create a dynamic, or 'time-stepping' model, starting with a set of

*Consider the
tablecloth trick.
The force applied
to the cup and saucer,
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equations which describe the forces on each device component at any position. At time zero, we can then determine the initial accelerations of each part, and if we assume that these forces stay constant for a very small amount of time (e.g. 0.0001s), Newton's laws of motion can help us determine the new positions of each component after that small time step. We then recalculate the forces for those new positions, work out the new accelerations and new positions, recalculate the forces, and so on for as long as we want. This is all automated in software, and all happens very quickly.

Of course, you need to check that the mathematical model predicts what is happening in real life – to validate the model to some extent – but we can do this through physical testing and observation, and discrete calculations and analyses. Once we are confident about our model, we can use it very effectively to investigate the sensitivities of our system, using virtual Taguchi experiments if appropriate, and hence make confident predictions about whether or not our cup and saucer will remain intact – and about what we need to change to ensure that they do! Sensitivity analysis is a powerful design tool, allowing you to predict the behaviour of your device when subjecting it to a design change, and can be done early in the design process, enabling you to refine your design from the start and avoid pitfalls.



A combination of ‘back-to-basics’ mathematical modelling, some FEA, and the application of Taguchi principles, can keep your design on track and help you solve problems with minimal cost, time and disruption.

Case Study: Auto-Injector troubleshooting

Recently, Team was asked to assist a client with an auto-injector in the very late stages of production, which was reporting a failure in a particular performance characteristic. Unfortunately, as there were only a few reported cases, the failure was difficult to measure, and the client was very limited as to what design aspects could be changed. On top of this, big deadlines were looming. The client needed an investigation into the causes of the problem, suggestions for potential design solutions which could be implemented quickly, or to know if the problem was large enough to stop the programme.

It was very difficult, if not impossible, to predict device operation by looking at the individual component models or subsystems alone, as the force on each component varied through time depending on where the other components were.

This was a prime candidate for a sensitivity analysis: the device seemed to work, but something was causing it to occasionally not work. By conducting a sensitivity analysis we aimed to determine the effects of component tolerances on the device performance (in case it was a tolerance issue), find

out the design aspect with the biggest impact on the performance parameter of interest, and determine how much an aspect of the design (such as a component dimension) had to be changed in order to prevent the device from ever failing.



Physical experiments could be conducted using production parts and devices, but not a sensitivity analysis, as it would be too costly and time-consuming to produce a myriad of parts all with slightly different dimensions or characteristics. Also, at this stage we did not know which parts we wanted to change or by how much.

The first step was to build an FEA model of the device and run simulations, starting with individual features and simple deflections. We used the CAD data to generate the model, and physical experiments on individual parts confirmed system characteristics such as material stiffness and friction coefficients. We then developed the FEA into a more comprehensive model, incorporating non-linear and dynamic elements, to assess performance of the combined system.

At this point, two issues occurred. Firstly, the FEA simulation did not agree with real life, shown by comparing simulation results to High Speed Video footage of the injector; in the video, the sequence of mechanical events within the device was consistently A then B then C, but in the simulation it was A then C then B. Although possibly able to determine why this was happening, we were faced with the second problem: the run time for each FEA experiment was extending into days. So even if the FEA simulation was accurate, it would be completely impractical for a sensitivity analysis which requires many such experiments.

We then turned to mathematically modelling the components and subsystems of the device to see if we could gain any further insights. We created separate mathematical models for each component of interest, describing the forces it was under throughout its range of motion, but it was very difficult, if not impossible, to predict device operation by looking at the individual component models or subsystems alone, as the force on each component varied through time depending on where the other components were. If we ignored the fact that the parts were moving with speed and just considered the forces on the parts, it would give the impression that the FEA model was correct, i.e. A, C, B. However, we suspected that the “table cloth trick” might be happening, and that it was all about the speed at which every component was moving.

We needed to stitch the models together, and add the element of time. The mathematical models, written in MathCAD, were combined in one larger

model with a time-stepping loop, as described above. Using this approach, we were able to predict the relative positions, velocities and accelerations of all the components during the whole injection sequence. We then confirmed that the time-stepping model was giving valid and accurate results by comparing its predictions with the performance of actual devices recorded with High Speed Video.

We then changed aspects of the device design in the time-stepping model to see how those changes affected the movements of the components. We set up and ran our virtual Taguchi experiment, and as each run only took seconds, we could run as many experiments as we wished.

We were able to predict the relative positions, velocities and accelerations of all the components during the whole injection sequence.

The client could only make specific alterations, and so we only simulated these alterations using the time-stepping model. We ran more than forty experiments, and used Minitab's statistical tools to show which aspects of the design had the greatest impact on the performance characteristic we were looking at. Once we had identified the best candidate for alteration, we simulated the effects of that change using the mathematical model before going back to the client with our suggestion on how best to solve this particular problem.

The mathematical model predicted (and the High Speed Video confirmed) that the problem would always happen to some degree, but we suspected that the difficulty in spotting the event meant that only a few were noticed and reported.

An approach for analysing a multi-component, dynamic device:

1

Describe individual components in terms of fundamental engineering and physics equations, i.e. mathematically model the individual components.

2

Make FEA virtual models of those individual parts.

3

Use physical testing of real parts to check the mathematical and FEA models and to get material characteristics.

4

Run FEA simulations of individual parts (i.e. simple forces, no interaction) to cross check that design changes in the virtual world and mathematical model have the same effect.

5

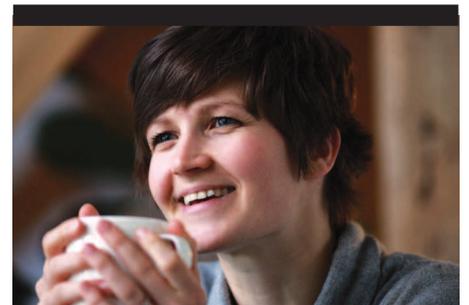
Tie the individual mathematical models together using a time-stepping simulation.

6

Run a sensitivity analysis, using DoE for experiment structure.

7

Use statistical tools such as ANOVA to pick apart results.



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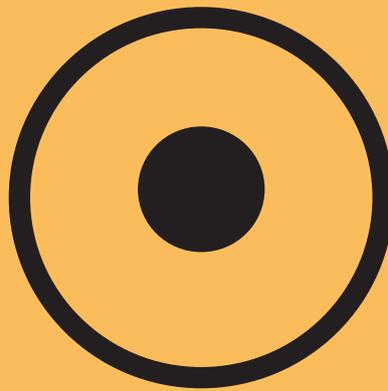
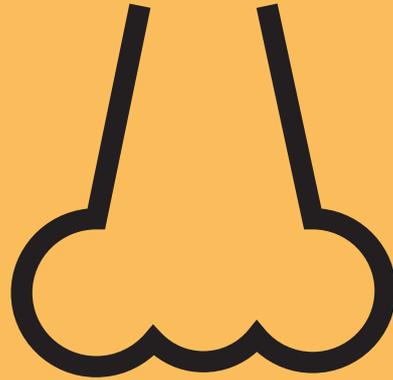


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Team / insight.

Multi-sensory experiences

BY NATALIE SCOTT



A hot topic in medical device development at the moment is improving the holistic user experience, but what does this actually mean?

There are so many different types of experiences that people can encounter with the same device and every time someone interacts with a product they will 'experience' something, whether the user experience is specifically designed or not.

There are many aspects that influence an individual's experience of a product, some of these you can control and some you can't. First and foremost you need to make sure that you deliver the right product (the right features, right shape and right size), to perform the required functions and meet the practical and lifestyle needs of the target users. To do this you need to consider the following five Ps: the Purpose, People, Place, Product and Process.



The five Ps can be used to explore and build a comprehensive set of use scenarios (including most likely, worst case and potentially stressful scenarios) to inform, guide and challenge development activities accordingly and ensure that the right product is developed. Now that we're confident that we're developing the right product, we should not ignore the importance of building an emotional connection with the user, which is particularly relevant in our industry, where people would quite simply prefer not to have to use a medical device. But how do we deliver a positive user experience?

HOW DO WE DELIVER A POSITIVE USER EXPERIENCE?

We perceive our world through our five senses (sight, hearing, touch, smell and taste). When using products, we make a series of conscious and subconscious judgements based on our sensory interpretation and response. For example, some visual cues can subconsciously communicate intended interactions, whilst some audio clicks are consciously used to provide feedback for correct use. It is important to understand all potential responses and interpretations for all the relevant senses throughout a product's life, to ensure that the right messages are communicated to the user at the right time. Mapping this holistic sensory journey not only leads to a more engaging experience from an emotional perspective but can also deliver more effective product outcomes in terms of user performance and compliance. Sensory mapping is crucial for users with some degree of sensory impairment, where there is a stronger reliance on the other senses. It is therefore important to understand the impact of certain conditions on sensory ability and design the sensory journey accordingly to provide appropriate feedback and prevent incorrect use.

SIGHT

Medical device manufacturers are becoming increasingly aware of the importance of a product's visual language as appropriate visual cues not only lead to more aesthetically appealing products, but can also improve a product's usability. There are many visual components to be considered as part of the visual design language, including product form, semiotics / semantics, aesthetic style, colour and material finish.

At different stages of the product life cycle, different types of visual cues become more important. For example, a user often forms an opinion about a product within the first few seconds of seeing it, and this first impression can often dominate their overall product opinion and experience. This first impression is usually based on their visual perception and so it is important that the appropriate messages are communicated from the outset.

It is also important that the visual language remains consistent throughout the product lifecycle and across all elements, including brand values, packaging, instructions, customer support and any other potential user touch points. The messages communicated should be complementary to avoid a confusing experience.

Individual users naturally develop their own mental models for product use based on previous product associations and experience. It is therefore important to explore similar devices and understand the associations that users may have with different colours, shapes, symbols, features and layouts. Depending on the market saturation of other products, it can sometimes be more detrimental to user safety to fundamentally redesign an unintuitive user interface, than to progressively improve key elements.

Another important aspect, often overlooked when entering new markets, is to explore and understand the different cultural associations that exist.

TOUCH

As the user starts to interact with a product, 'touch' and 'feel' become the more dominant senses. 'Feel' encompasses the physical form and materials used (often associated with touch), and also the motions, forces and other tactile characteristics which can significantly impact on ergonomics and usability.

Product users with a visual impairment will rely on feel, associated sounds and - where applicable - smell to provide essential guidance and feedback regarding correct use. Therefore, all the physical touch points should be mapped and explored to ensure that any interaction is consistent with user expectations and other perceptual themes.

Just as certain visual properties can communicate different messages (such as 'premium professional' quality or 'approachable'), the feel of the materials used and the tactile feedback from any moving parts can further support these themes. It is often difficult for users to articulate these particular preferences or associations, but different subliminal messages and characteristics can be communicated through the touch and feel of forms, motions and surfaces.

As well as device ergonomics (the overall shape or form of a product), it is crucial to consider all other physical touch points such as buttons, levers, handles, moving parts, keypads, grips, or touch screens. Surface quality (different textures, geometrical features or surface forms) can provide valuable guidance for use in terms of where and how to hold the device, as can the character of actions and moving parts. These can also convey different quality messages depending on the level of resistance, speed, consistency, and the specific path of the motion, and can also provide feedback which may influence user behaviour. An unintentional change in the character of a motion could therefore lead to incorrect use; for example, if a user plunging a syringe suddenly feels a resistive force, they may assume that the injection is complete, when in fact the force may be the trigger of a safety feature.

HEARING

Sound can provide a range of feedbacks: that the device is working; that an action has been successfully completed; a warning that the user has done something wrong; or an alert or reminder. Sound can have a powerful influence on our holistic perception of a particular experience.

The subtleties of characterising a sound can be very complex and very different messages and tones can result from the loudness, timbre (tonal quality), frequency (pitch) and duration of the sound used.

The characteristics of the sound used should therefore reflect the messages to be communicated, and other perceptual product themes. For example, if a product communicates very soft, gentle and approachable messages through its visual language and tactile qualities, sharp, high-pitched sounds, harsh to the ear and annoying, are inappropriate for general feedback cues. However, a warning or alert should be distinctly different in its nature and tone, and difficult to ignore compared to sounds used for general feedback.

HEARING IS ONE OF THOSE SENSES THAT IS OFTEN SUBCONSCIOUSLY USED

Some sounds can also fade into background noise after a prolonged period, such as the continuous drone of an aeroplane. Therefore it is important that high priority messages relating to safety are quickly recognised and cannot be ignored.

Hearing is one of those senses that is often subconsciously used but can have a powerful influence over our holistic perception of a particular experience.

For example, some car manufacturers spend a large amount of money and effort researching and engineering the car door catch to ensure the sound it makes when closing the door communicates the appropriate perception of quality. Although it may appear a minor factor in the bigger picture of car design and engineering, it is often the combination of all these relatively minor aspects which build the holistic experience and leave a lasting impression with the user.

It is also important to consider the unintentional sounds produced by other functions as these clicks, squeaks and rattles can often be misleading and can lead to user error. For example, when using an auto-injector, if a click is produced midway through drug delivery because another technical function is activated, this may be misinterpreted as a feedback cue for the end of the process, and as a result the user will not deliver the full dose.

Sounds can also draw unwanted attention. Most asthmatics, for example, want their inhaler use to be discrete, and so it is important to minimise and control any sounds given off during inhalation as these could reduce user motivation.

OLFACTORY

There are many examples where smell provides useful guidance for product use. For example, the preservative m-cresol in insulin has a very distinct anti-septic smell; visually impaired diabetics use this strong scent to indicate that the insulin has passed through the needle tip and the device is 'ready' to inject.

Research shows that smell has strong emotional connections; scent messages are carried to higher brain areas involved in conscious discrimination and perception of odours, and can trigger more primitive areas linked with emotions such as fear, loathing, love, and happiness. Smell also has very powerful connections with memory, which can have a significant influence on product experience (if used incorrectly),

although it is often difficult to define and recreate particular odours, and emotional associations are often linked to personal experiences.

Some asthma patients use taste to indicate successful inhalation of their drug medication. Lactose, often used as a drug carrier in DPI formulations, is deposited at the back of the throat during inhalation leaving a sweet taste in the user's mouth, and is often used as an indicator that the drug has been received.

If medication or drugs are to be taken through the mouth or nose, then the impact of smell and taste of the drug on the overall user experience cannot be ignored.

Other drugs that have a distinct smell can also affect the user experience and perception, especially those with a smell or taste that provokes emotional barriers to use by triggering negative memories associated with a particular smell or flavour.

Careful consideration of a user's sensory journey can ensure the intended messages are delivered and can prompt the right product outcomes, leading to a more emotionally engaging user experience helping improve user motivation and hence increasing user compliance. Therefore, these relatively minor, apparently 'low risk' product characteristics are more important than many development teams realise, and can have a significant impact on ultimate product compliance.



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SOME LIKE IT HOT

BY BEN WICKS

In the last edition of *insight* Ben Wicks wrote about the emerging field of therapeutic hypothermia. In this article the focus is on heat-based treatments which have the potential to cure some important diseases.

Team / insight.

The world's big pharmaceutical companies are already under pressure from generic competition and the demise of blockbuster drugs. If that wasn't bad enough, a new category of therapeutic interventions is becoming established, able to cure problems which were, up until now, continuously treated using drugs.

FIXING ASTHMA — BRONCHIAL THERMOPLASTY

Most people are familiar with inhalers for managing asthma. We've developed a few here at Team. Every day millions of people take asthma drugs to reduce the constriction of airways which causes shortness of breath and wheezing. Nobody is 100% certain why the airways in the lung are surrounded by a tube of muscle which can contract and cause this constriction. What is certain is that muscle constriction can be a big problem for asthmatics, in some cases even fatal.

For many years, researchers have been exploring ways to treat severe asthma and in the late 1990s scientists began to explore the seemingly crazy idea of heating the bronchioles (the tubes which carry air into the lung) to 'cook' the smooth muscle in the airways and stop it constricting. The idea sounds painful and dangerous but research showed that heating the bronchioles to ~65°C would permanently damage the smooth muscle but not destroy the delicate lining.

It was a scary step to take the procedure into humans as, after all, the intention was to cause permanent damage to the patient's lungs. There were two main concerns. Firstly, could the heat treatment be applied without causing collateral damage and trauma to the airways of an asthma patient who already had difficulty breathing? Secondly, would any long term deleterious effect occur if someone's airways were no longer able to constrict?

The first human trial was cunningly done on a group of eight patients who were scheduled to have a chunk of lung (a lobe) removed because it was potentially

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cancerous. The treatment was carried out via a bronchoscope (a camera on a thin tube) pushed down into the lung. A small balloon catheter, with four external wires, was extended into the bronchiole and inflated. Once the wires were pushed against the inside wall of the bronchiole, a 10 second electrical pulse of RF (or radio frequency) energy was delivered, heating the surrounding tissue.

The airways leading to the suspect lobe were heat treated several weeks before the lobe was surgically removed and results showed that bronchial thermoplasty could be safely tolerated. In addition, when the bronchial tissue was examined under the microscope the scientists could see that the amount of smooth muscle was significantly reduced.

Almost a decade has passed and this technique is gradually becoming adopted more widely. The emerging body of evidence seems fairly compelling, and shows that there is some benefit in doing bronchial thermoplasty, although it isn't an immediate or complete cure.

We now have data gathered from patients up to six years after treatment. Some proper clinical trials have been undertaken and the procedure is beginning to be approved and adopted. There remains a lack of evidence about the long term implications, hence the clinical community remains understandably cautious.

The whole procedure only takes about 30 minutes and the damage to the lining is barely visible and is repaired within a few weeks. The therapy is normally applied in three separate sessions with a gap of about a month between each session to allow the damaged tissue time to recover.

The results are extremely impressive and appear to be permanent with patients experiencing a reduction in symptoms and in medication. There is a small but non-trivial risk that long term problems may appear, say after 20-30 years, but as yet no such problems have been identified.

At present, bronchial thermoplasty is only being used on the most severe asthma patients who don't respond to drug therapy. Adoption will probably increase beyond this group but it is unlikely that thermoplasty will ever be used to treat all asthmatics. The impact on sales of asthma drugs is currently small, but as the procedure gains adoption it could have a measureable impact.

FIXING HIGH BLOOD PRESSURE — RENAL DENERVATION

High blood pressure is a huge health problem, and a significant contributor to the heart, lung and kidney diseases which consume such a vast amount of healthcare resources. Whilst diet, lifestyle and drugs all play a part in managing blood pressure, there are patients whose blood pressure can't be controlled.

Blood pressure is regulated by the autonomic nervous system – the bit you and I (thankfully) don't have to think about. Nerves which connect the brain to the heart and to the kidneys play a key role in regulating blood pressure.

In the first half of the 20th century, scientists investigated whether disrupting the autonomic nervous system would affect blood pressure, and found that by cutting the nerves running to and from the kidneys high blood pressure could be reduced. Unfortunately, as the nerves supplying the kidneys run alongside the large renal artery which delivers blood to the kidney, the only way of cutting the nerves was to cut the renal artery and then re-join it again, thereby severing the nerves (which didn't regrow and reconnect).

Fast-forward half a century and the discipline of interventional radiology is now well established, with large blood vessels routinely used to gain access to a range of organs so they can be diagnosed and fixed. In the late 1990s, researchers began to investigate whether the renal nerves could be inactivated from inside the renal artery, and as a result developed the RF energy delivery catheter and balloon



**IN 2010,
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TECHNIQUE.**

system, very similar to the bronchial thermoplasty system. The catheter is inserted via the femoral artery up into the renal artery, the balloon is inflated and delivers heat from inside the artery to damage the nerves running along the outside.

The medical device industry is highly excited at the prospect of a new therapeutic device to treat high blood pressure. In 2010, Medtronic paid \$800 million to acquire Ardian, the pioneers of this renal denervation technique. Since then, most of the major medical device players have acquired companies or technology in renal denervation, and venture funding is flowing into new companies developing the procedure.

In the long term, this treatment will definitely have a significant impact on sales of blood pressure monitoring drugs. Some pharma companies are already making significant investment in potential new therapeutic device technologies. This seems a prudent move - while finding new blockbuster drugs is getting ever more difficult, the world of interventional medical devices seems ripe for innovation.



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Team / insight.

A World First in Liver Transplantation



Make this article come to life on your smartphone or tablet, by downloading the **Team AR app**. Hover over the image below to watch a 60 second trailer for our documentary on what we did for OrganOx. You can watch the full length film here: team-consulting.com/organox

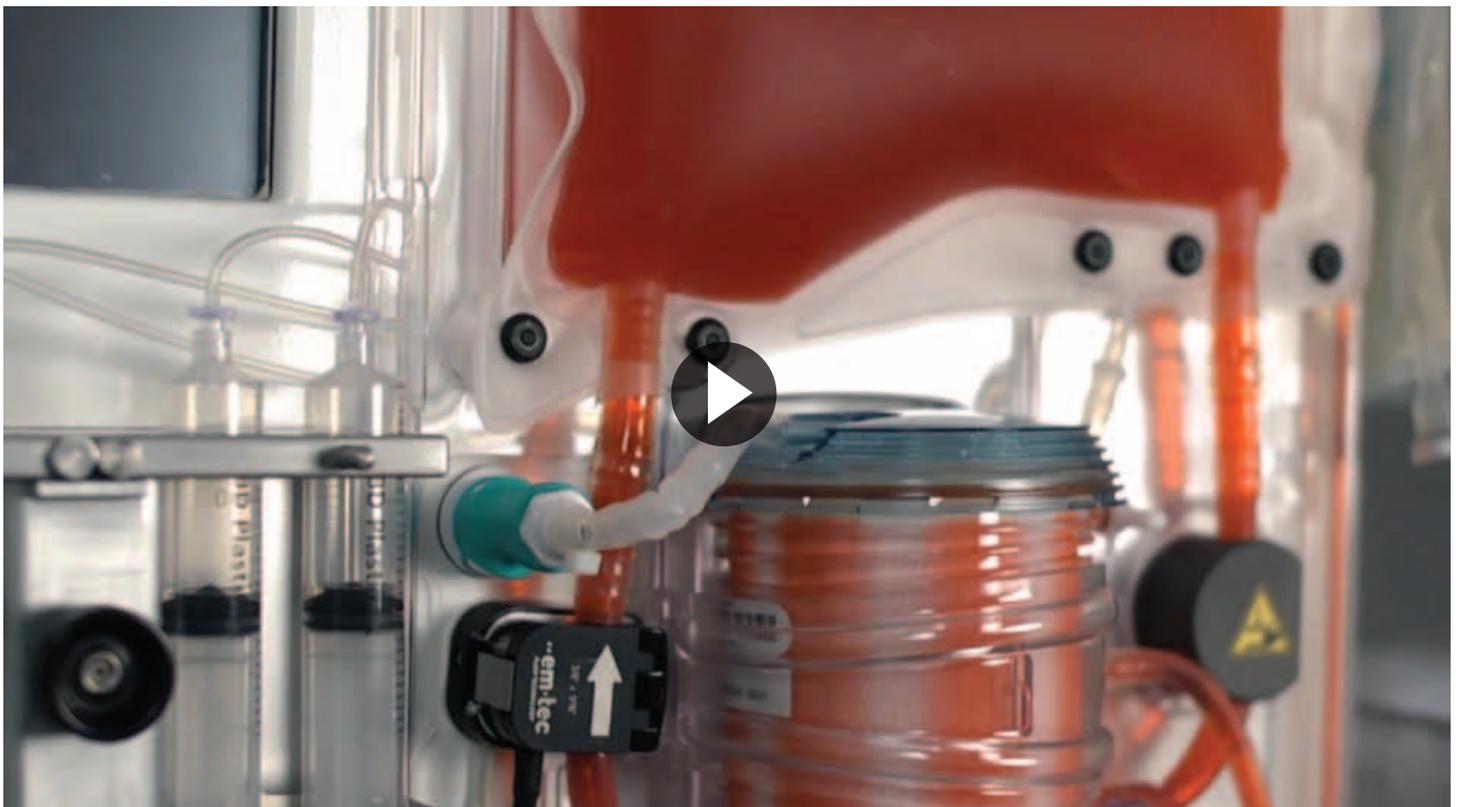
Although Team's work has often paved the way for step change innovation, rarely has it generated the level of international publicity recently received by Team's client OrganOx Limited.

In March 2013, the University of Oxford and King's College Hospital, London announced that they had kept a human liver alive and functioning outside a patient's body

before successfully transplanting it into a new patient – and had done this twice. This 'world first' was achieved using the OrganOx™ *metra*™, an auto-regulating normothermic liver perfusion system devised by OrganOx and designed by Team.

The *metra*™ represents a real advance on current clinical practice where livers are retrieved, flushed with a cold preservation solution, packed on ice and then rushed between donor hospital and transplant centre, with the result that many livers are discarded due to logistical constraints, an inability to assess liver quality, or organ damage resulting from being placed 'on ice'. By preserving liver quality for an extended period of time — up to 24 hours — the system could double the number of organs available for transplant by preserving the quality of organs which before would have been declared unsuitable.

Designed to maintain the liver in a fully functioning state during transport and storage, the *metra*™ provides blood flow, oxygen, carbon dioxide control, nutrients and temperature control within





physiological parameters, while also monitoring factors such as bile production. By mimicking the body, the system can potentially store the liver for up to 24 hours while providing real-time and cumulative data which the surgeon can use to assess liver function and viability, something which has never been possible before.

The development process began in 2009 when OrganOx, a University of Oxford spin-out, appointed Team to assist in the design and development of the system in order to move from proof of concept to commercial manufacture. 'When first set up, OrganOx was a very small company, closely linked to the University, and it needed system design and development capability in order to take its invention 'from bench to bedside', explains Stuart Kay, Team's Head of Electro-Mechanical Engineering.

'These first clinical cases confirm that we can support human livers outside the body'

'Our primary focus was to turn the original, large, manual, clinician-dependent process into a robust, autonomous system controlled by embedded multi-tasking software with a safety-critical architecture — which meant that if a peripheral system component failed for any reason then the core system would continue to function. We had to create a small system which could survive road and air transport, a wide variety of weather conditions as it was moved around, and also — of great importance — a system which was quick and easy to set up and use, despite its complexity and sophistication.'

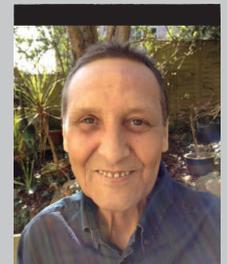
Team supported OrganOx throughout the core design and development phases until verification testing activities had been completed. While the complete process took four years between the original meeting and MHRA approval to conduct clinical trials, Team delivered the first fully autonomous proof of principle system in just nine months, which helped OrganOx secure further funding. The first transplant took place as part of a controlled clinical study at King's College Hospital in London, home to Europe's largest liver transplant centre which carries out over 200 transplants every year. It is hoped that the device could be useful for all patients needing liver transplants, and Professor Constantin Coussios, OrganOx Technical Director and one of the system's original inventors, is delighted:

'These first clinical cases confirm that we can support human livers outside the body, keep them alive and functioning on our machine and then, hours later, successfully transplant them into a patient. The system is the very first completely automated liver perfusion device of its kind; the organ is perfused with oxygenated red blood cells at normal body temperature, just as it would be inside the body and can, for example, be observed making bile which makes it an extraordinary feat of engineering. It was astonishing to see an initially cold grey liver flushing with colour once hooked up to our machine and performing as it would within the body. What was even more amazing was to see the same liver transplanted into a patient who is now walking around.'

Mr Wayel Jassem, Consultant Liver Transplant Surgeon who performed both

transplant operations, was also impressed: 'There is always huge pressure to get a donated liver to the right person within a very short space of time. For the first time, we now have a device that is designed specifically to give us extra time to test the liver, to help maximise the chances of the recipient having a successful outcome. This technology has the potential to be hugely significant, and could make sure livers are available for transplant and, in turn, save lives.'

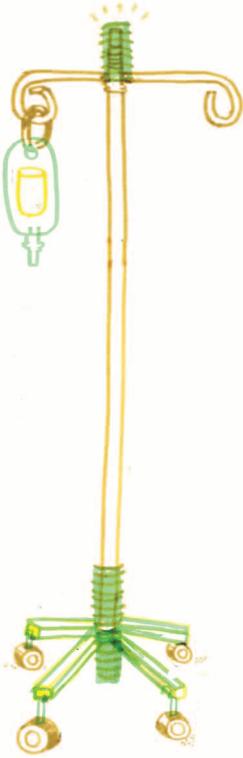
Team's Stuart Kay explained that the system could also provide a platform for future development. 'We have designed a safety-critical system which is robust, reliable and simple to use, and which meets some very demanding requirements. A system of this type had never been attempted before, and is a testament to our design and engineering capabilities and to the dedication of the whole project team.'



Ian Christie (62) was the first person to receive a transplanted liver kept alive by the OrganOx™ metra™ system as part of a controlled clinical study:

'In May 2012, I was told I had cirrhosis of the liver and without a transplant I had an estimated 12-18 months to live. I was placed on the waiting list but I was told there was about 12-18 months to wait for a liver of my type. I was very worried it was cutting it a bit too fine and I wouldn't get a transplant. The waiting is horrible ... You're waiting for the phone to ring, wondering: Are they ever going to call me?'

'I took part in the trial because if the device can help more people in my situation in the future, it's my duty to help. I feel better than I've felt for 10-15 years, even allowing for the pain and wound that's got to heal. I'm getting better day by day. I just feel so alive!'



Design research is the process we use to discover new ways to make things better ... ways we can enhance people's lives and develop new business opportunities for our clients.

There's really very little magic to design research. The techniques are simple and obvious and, as my old IDEO colleague Jane Fulton Suri suggests, a lot of people have them and they can easily be taught. What is harder, and what makes designers different and valuable, is knowing how to use the information these techniques generate. It's easy to create mountains of data, but really hard to extract some value from them. Or, to put it another way, it is massively beneficial to see what everyone else has seen yet think what no one else has thought.

As an example, we thought it might be worth spending some time with a piece of medical equipment that everyone looks at but no one really sees — the humble IV stand.

So we spent a few hours in hospitals, watching and talking with people, listening to their stories and being aware of what was happening around them.

GRIME AND THE GRIM REALITIES

They are a bit like shopping trolleys, except you don't have a choice. If you're unlucky enough to be given one with a wonky wheel, you simply have to learn its errant ways, holding onto the pole at waist height with one hand, perhaps while also trying not to spill a cup of coffee.

The wheels are not spinning freely because of years of congealed and compressed detritus and an almost complete lack of maintenance. Ecologists might call it another 'tragedy of the commons' – the ruin of a shared resource through rational self-interest.

This pole is nobody's. Probably four or five people have some management responsibility for it; the net effect is that no one has. Nobody cares for it, why would they? It's not glamorous high tech for which he have technicians; it does nothing medical, so why would nurses maintain it; nor is it strictly furniture or infrastructure, for which we have facilities people.

It stands in the corners of wards waiting to be pressed into service. Its ubiquity is its downfall. It is not special, or demanding or even scarce. It is overlooked and under-loved.

ROCK AND ROLL

Watch people try to walk with their stand and you realise that, despite the wheels, they are not designed to be mobile. If they were, perhaps you could stop the wheels from castoring, to give more control; or one wheel might be fixed in the straight-ahead; or the base would present less of a trip hazard; and there would be a handle or some way to exercise control.

The slightest change in floor level can stop a stand in its tracks. Door thresholds, sealing strips, lift entrances ... all have to be approached with care. The wheels are small enough to fall into these slots or to stumble over ledges.

If you are frail – and surprise, surprise, many people in hospitals are – then you might look to this upright piece of metal for support. You would be foolhardy to do so.

We spoke with a gentleman whose saline drip made him need the toilet frequently. He had to take his stand with him but its small, errant wheels were extremely difficult to control. He used the conveniently placed adjustment knob at waist height to gain some control but not designed for that purpose, over time it slackened and the whole structure collapsed to half its original height. The saline bag was now at the level of his heart and promptly filled with blood.

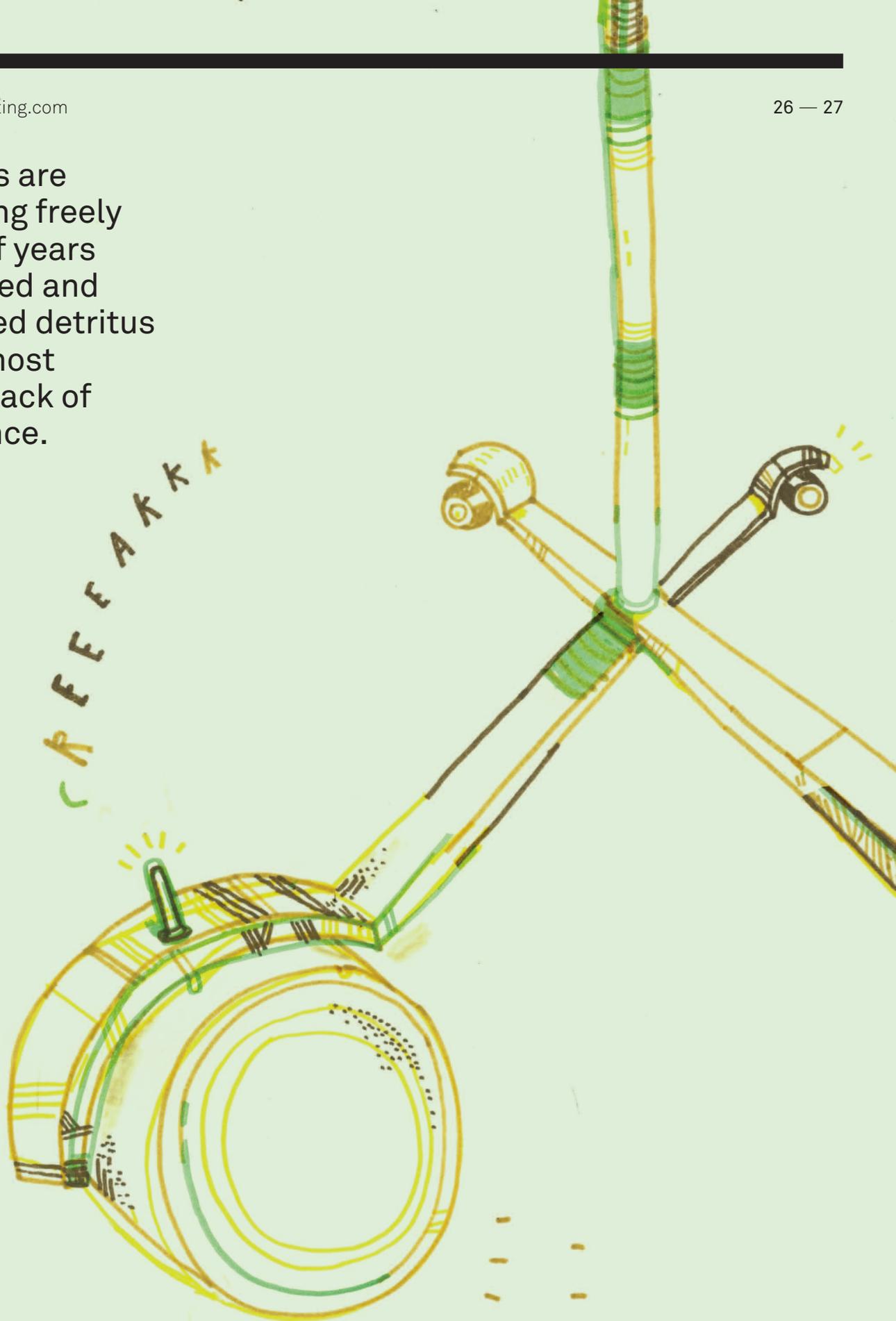
Perhaps you can empathise? In a public corridor, desperate for the toilet, naked except for a thin hospital gown, watching as your blood leaves your body.

To compound matters, this gentleman was told off for walking around and creating this situation. The IV stand, despite having wheels, decreases mobility which somehow people seem to accept. He felt conspicuous walking about, as few other people seemed prepared to battle with their stands. Busy nurses would prefer people to take themselves to the toilet yet find themselves persuading them to stay still and ask when they want

LOOK, DON'T JUST SEE

BY **MARTIN BONTOFT**

The wheels are not spinning freely because of years of congealed and compressed detritus and an almost complete lack of maintenance.





help. And at the centre of this dilemma is the humble IV stand, which doesn't mean to disempower or demean but finds itself doing so.

He had to take his stand with him but its small, errant wheels were extremely difficult to control.

HOW DID WE GET HERE?

The nurse's experience is equally bleak. They have to load the stand with fluids and equipment, sometimes to the point of instability and typically in the worst situations as usually the most seriously ill need most fluids and devices - the last patients whose care needs interrupting by a collapsed IV stand.

They are also the most likely to need a rapid transfer to the emergency room, where often a nurse - a motivated and highly trained healthcare professional - is needed to push the stand, manage the wheels and make sure that bags, cables and lines don't snag on anything they pass.

The nurses' commentary was about how poorly the stand enables or supports the most basic of tasks, and how they cannot access all of its parts to clean it effectively.

The ward we visited had three different types of stand, each had its own characteristics and disadvantages, and none worked well together. With different numbers of legs they didn't nest or overlap, they took up room, they got in the way of good care and ended up being kicked and damaged in frustration.

How do we get to a situation in which the most basic requirements of these stands are not met? What does this say about the methods of hospital procurement?

I'd further suggest that the Victorian doctors who pioneered intravenous therapy would probably recognise the IV stand, if little else about modern medicine.

THE CONSTANT COMPANION

Over all those years, the IV stand remains the one piece of hospital equipment that follows the patient everywhere, in many cases all the way from admission through to discharge.

We heard how the patient would be hooked up to the stand, but not shown how to manage it or the bags and lines. People told of sleeping in a fixed position because they were so concerned that moving might interfere with the security of the lines and connectors.

One man told of waking in the night with a pain in his side from sleeping on top of a connector; when he moved to get comfortable the connector came apart and he and the bed were drenched in his urine.

Tethered to an IV stand, sensitive parts of the patient's body are attached by thin, strong lines to several kilograms of metal which not only reduces mobility and dignity, but enters consciousness in other ways.

Patients are unaware how the lines from the stand that arc across to their bodies are attached, how they stay in place and what they can or cannot do while they are there; all they know is that a sensitive part of their body might hurt if they make the wrong choice. People tell of the care and attention they focus on these lines, knowing that in a sense they are an extension of their body.

We were also told about the simple joy of fresh clothes after being in a hospital bed for several days, and the contortions necessary to put them on, with the IV stand becoming a staging post in something akin to a public game of Twister.

Peter, one patient we met, shared with us his thoughts about the stand that had been by his side during a long hospital stay. The relationship he forged with this imperfect companion was so strong he felt moved to write a poem about it, and to name it 'Lucrezia Borgia'.

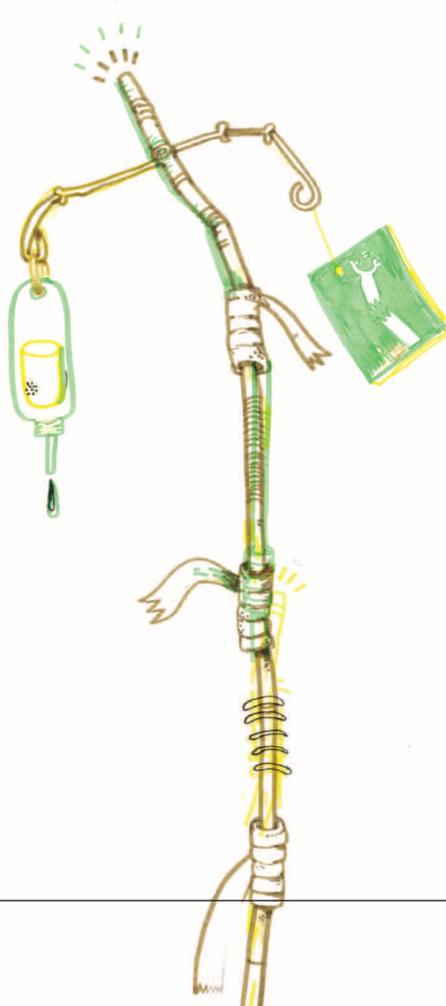
SO WHAT?

If our thinking has any significance it is perhaps that it helps us recognise something of the true nature and importance of the relationship between a user and the designed object. The IV stand may be a piece of metal, but it moved a man to write a poem. It is commonly held to be an unimportant receptacle for important things. It is, in reality, more than that right now, but maybe we can believe it has the design potential to satisfy that bigger role?

It could be reconsidered as a mobility aid, as a support structure for frail people which enhances rather than degrades mobility and autonomy.

It might be conceptualised as a 'partner' or 'supporter' that shares all the worst times of a hospitalisation. It could carry something of the patient's identity and personality, and could be customised functionally or personalised

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emotionally. It might then play a role in socialisation within the sometimes impersonal microcosm that is a hospital ward.

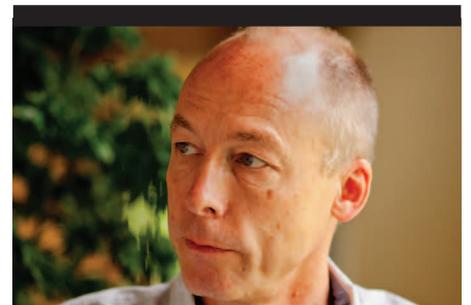
It at least exemplifies the fractured relationship between the buyers and users of this type of equipment, extending perhaps to the designers and manufacturers. There are design opportunities here too – creating the right processes for involvement and facilitating collaborative design work.

Lastly, we would at least make it easy to clean and move - more stable and maintainable.

Design research might be criticised for complicating what is simple, or for confusing the obvious, and there is an element of truth in that. It won't always generate new-to-the-world, commercial ideas, but it might. It's the best way I know to help designers and clients look at the banal and obvious and think something never thought of before - and that's how we innovate.

Acknowledgements

This couldn't have been written without the massive help of Caitlin Cockerton and Peter Banner, who both spent time in hospitals looking at drip stands from different perspectives.



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Martin heads up our design research group. He was Head of Research at IDEO for 10 years before running his own consultancy and then joining Team.

Graceful Shutdown

BY JONATHAN OAKLEY

Battery-powered and battery-backed systems are now so commonplace that even to remark on them feels incredibly old fashioned. We are all so used to charging our mobile phones, electric toothbrushes, game controllers and Bluetooth headsets that it has become as automatic as hanging up our car keys. And it comes as a huge surprise if we can't find the keys, or our phone has no charge. So much effort has been put into battery technology, both in terms of capacity and consumption, that battery life is now so good that it is rare indeed to find our phone flat.

And here we find a largely unconsidered corner of the battery life design equation – the graceful failure. What is actually supposed to happen when the power source can no longer support its host device?

For the electronic engineer this is a classic conundrum. Just at the time when energy becomes limited, we would like to warn the user of this – but we don't want to consume more energy doing so! An LED doesn't take much power, and is actually more likely to be noticed if it's flashing (thus consuming no power for some of the time); but it's no use if the device is in your pocket, or another room. Sound is good, but the user is going to get annoyed if woken at 3am with an alert that the toothbrush could do with a charge.

Even in the absence of a good warning strategy, there remains the problem of optimal shutdown. For your phone there's no major problem. Provided you don't lose all your contact numbers you're unlikely to worry too much and after all, in the end it's your fault the battery went flat. But for a complex medical system other choices could be made; by shutting down a power-hungry heater, for example, it may be possible to keep a vital oxygen-level control system running for a few precious extra minutes. At the very least,

one needs enough warning to be able to save the system state so that operation can resume cleanly once power is restored.

This requires input from the whole design team. Amongst the myriad of other considerations battery shutdown can easily get short shrift, along with adequate system cooling and labelling. Yet ignoring it can have enormous consequences, and leaving it until later will often limit the scope of what can be done, making it difficult or even impossible to then change a sub-system to a less power-hungry one, or even just to one that can be shut down on demand.

EVEN A SOPHISTICATED CHARGE-COUNTING SYSTEM, WHICH MONITORS CURRENT INTO AND OUT OF THE BATTERY, CAN COME UNSTUCK.

None of this is made any easier by the difficulties involved in monitoring battery charge state. Simply monitoring battery voltage is rarely sufficient, as it will vary with temperature and load. Even a sophisticated charge-counting system, which monitors current into and out of the battery, can come unstuck. At Team we have direct experience of this when using an 'intelligent' battery module. This came complete with charge counting, status communication and automated charge termination, but could suddenly go from



40% charge to 0%, shutting the system down without warning. The reason? It took several weeks to determine, but it turned out that the system would fail if put on charge straight after being brought into a building. The charge termination would sense the fast temperature rise, assume that it was due to the battery reaching full charge, and not only stop charging but set the status to indicate a fully-charged state – even if moments before it had indicated 30%!

So when designing any device or system reliant on battery power remember these key points:

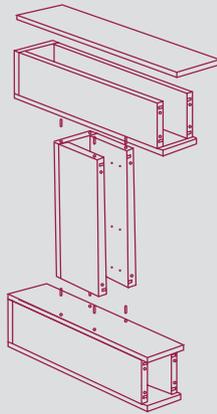
- As part of the design process, include a thorough review of which sub-systems might be shut down early as power levels fall
- Involve the whole design team
- Make sure you fully understand the charging and discharging regimes – and how these will work in the real world
- Don't leave it too late in the design process!



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Human Factors Engineering in Medical Devices

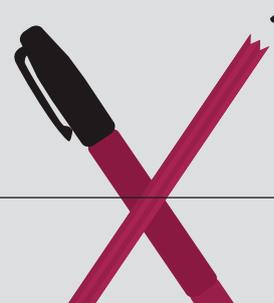
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An A–Z



“ Human Factors
is a game of words,
not a game of numbers ”

RON KAYE

Human Factors Pre-Market
Evaluation Team Leader, CDRH at the FDA



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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