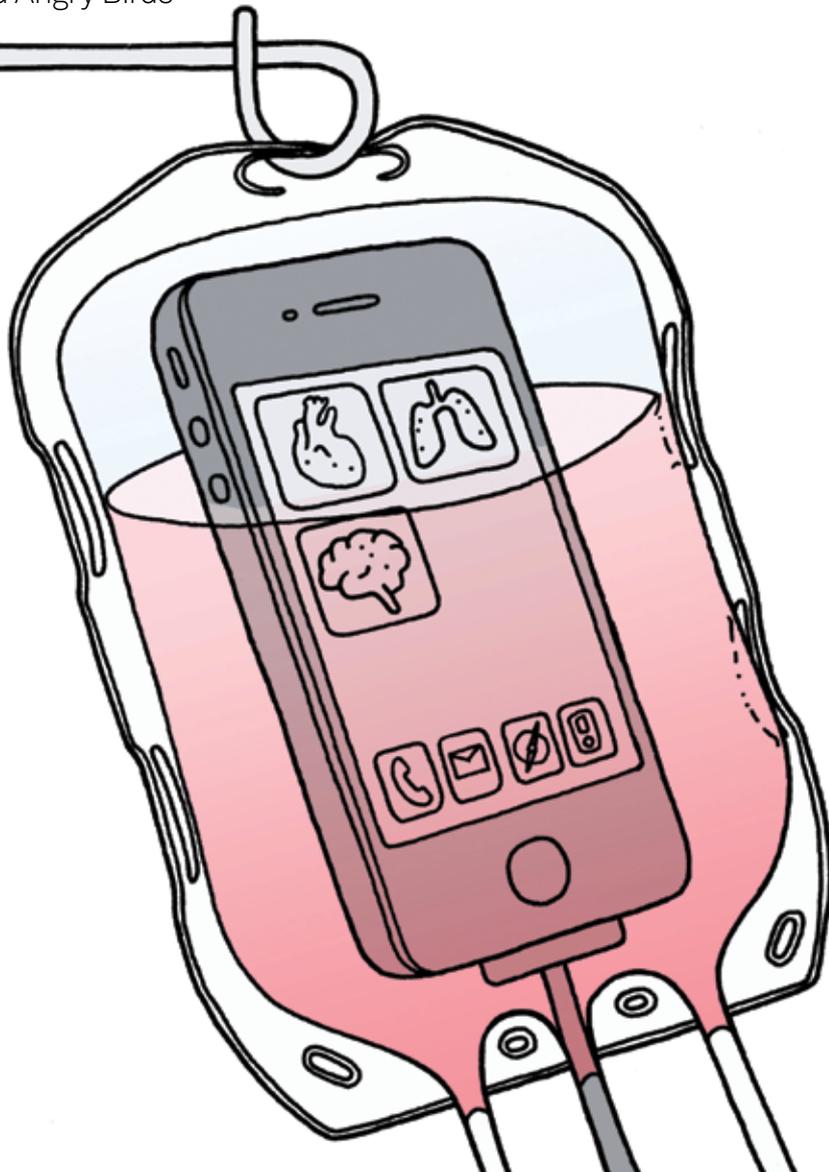

Can you live without your phone?

insight.
ISSUE No.3

Brennan Miles goes
beyond Angry Birds



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Sustainability in medical

Over tea and biscuits, Team's consultants discuss the challenges and barriers

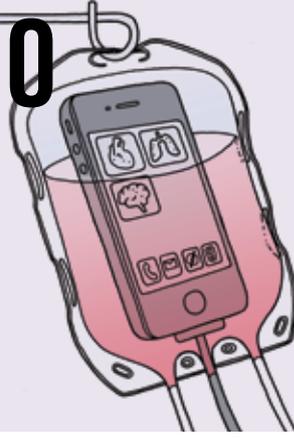
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CAN YOU LIVE WITHOUT YOUR PHONE?

The mobile phone, in particular modern smartphones, could play a key role in remote healthcare and the patient experience.

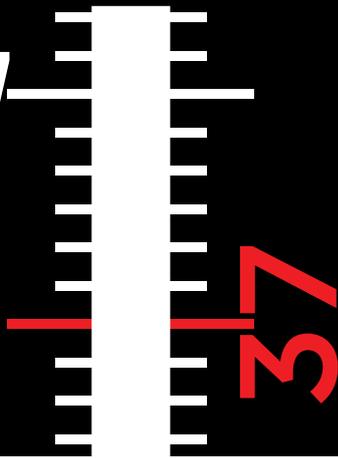
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SUSTAINABILITY IN THE MEDICAL DEVICES SECTOR WHAT DOES IT MEAN?

Although there is no significant market pull for medical devices to be sustainable, it is an issue that we all need to tackle. A group of us sat down to discuss the state of play.

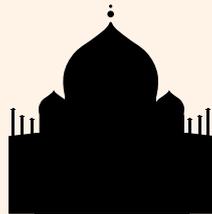
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THERAPEUTIC HYPOTHERMIA

Reducing the body's temperature, by just a few degrees, can significantly improve the chances of recovery in patients. However, cooling them down is not an easy process.

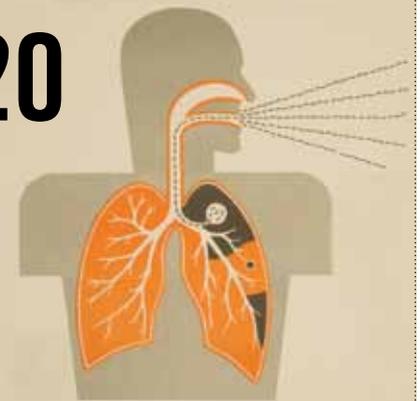
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India's growth trajectory over the next 40 years makes it an incredibly important country to do business with and in. Dan looks at the opportunities and challenges India faces.

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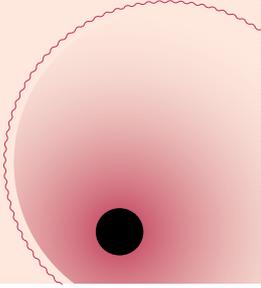


INFORMATION DESIGN FOR EFFECTIVE INSTRUCTIONS

We've asked Alison Black, from the UK's University of Reading, to talk about the importance designing important health information in a way that helps people.

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DESIGN'S TIME TO SHINE



GENETIC ENGINEERS AND MOLECULAR FACTORIES

DNA vaccines can help the patient fight the disease they are suffering from, but the challenge of getting synthetic DNA into the cells is one that cutting-edge science and clever engineering can overcome.

All change

BY **DAN FLICOS**

The only thing that is constant is that everything changes. And change brings new opportunities and new challenges. Whether that change is from advances in technology, from a rapidly expanding population or from increasing regulation, companies need to evolve to survive and to win.

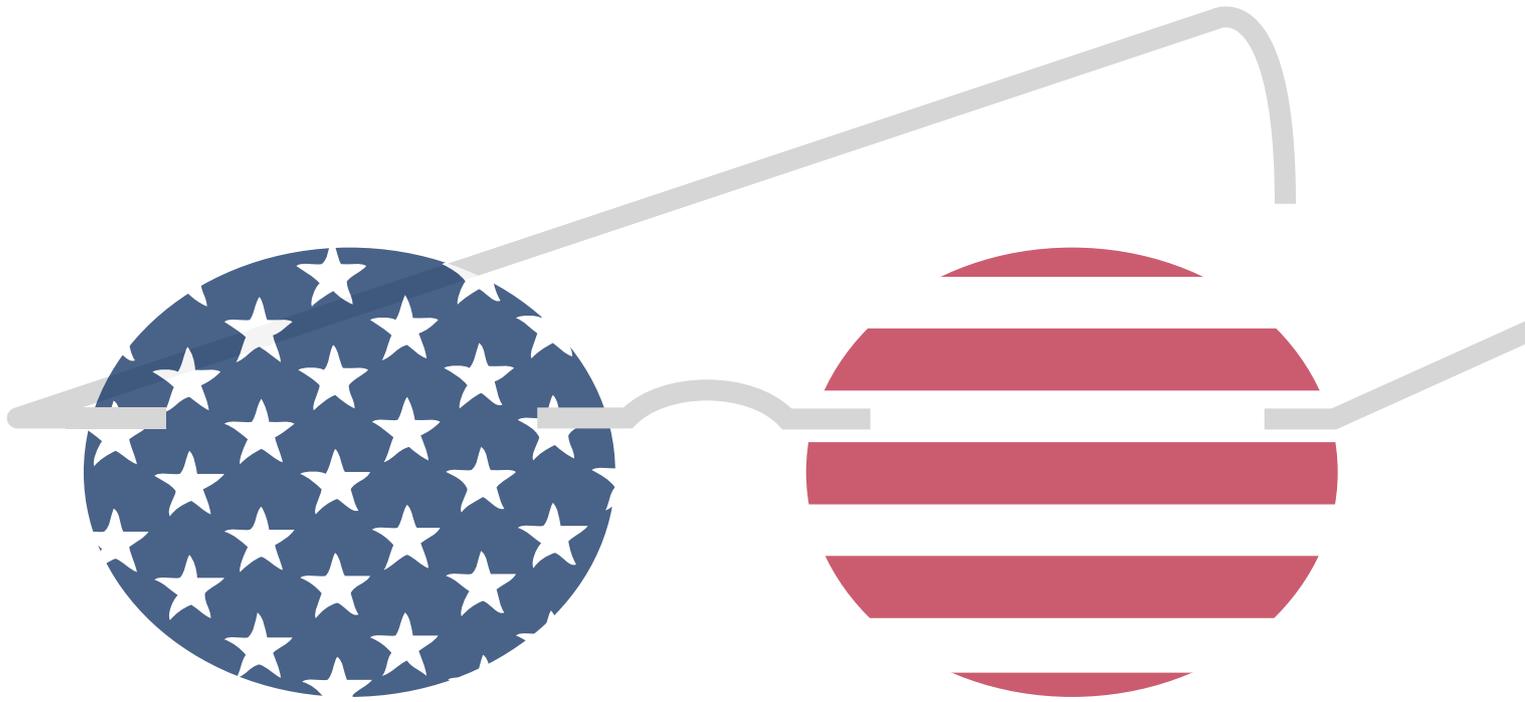
In this third edition of Insight, we look at some of the many ways in which change is affecting the medical sector. We look at the changing face of design and the impact of design research. We review some of the latest therapies and what they mean for the industry. Sustainability is a challenge for many sectors, and we consider what this might mean for medical companies.

So whatever changes you are facing, we hope you find this edition of Insight interesting and we would love to hear what you think.

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Credits

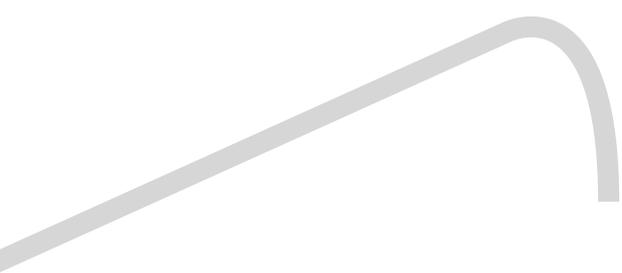
Editorial team:
 Neil Cooper / Angela Murray
Designed by: The District



DR: Design Research? No, Donald Rumsfeld

BY MARTIN BONTOFT

Donald Rumsfeld started me off. In 2002, he was trying to explain to an incredulous world the limits of knowledge about Iraq's supposed weapons of mass destruction; inadvertently, he clearly encapsulated something that had been troubling me for a while.



I had been leading IDEO London’s human factors and design research group, ensuring that people were considered from the very conception of a client’s project. Every so often, somebody in the team would surprise me with the design research they wanted to carry out. I recall having to go to the Connolly Leather shop for an office furniture project, and visiting an aircraft museum during a kitchen equipment project.

What surprised me about these research forays was both their random, unpredictable nature and that, despite this, they were immensely productive, informative and inspirational. What troubled me was that I had no idea how to do what some designers found so easy – how to go off piste and stay productive, how to take risks with research, how to look in places you didn’t know to look in, and still find relevance.

Rumsfeld talked about “known knowns”, the things that you know you know. He went on, talking about known unknowns, and while the rest of the world looked on aghast something started to come together for me...

	...that we know	...that we don’t know
What we know...	Assumptions	Gaps
What we don’t know...	Tacit knowledge	Discoveries

Design research is frequently concerned with the balancing of two demands – to both inform and inspire. This is driven by the need to innovate - to go off piste, but usefully. We don’t simply want novelty; we want ideas new to the world that have real value and relevance for people. To do this, design research has to help us find answers to the problems we know about but it also has to do more, it has to challenge, provoke and help us discover.

What we know we don’t know

In my experience, research tends to provide answers to the stuff we know we don’t know ... the gaps in our knowledge (and it’s the top right quadrant in the matrix that I want to explore). We are aware of these gaps and we know what to do about them; we know the questions to ask and we simply have to find the information we need.

This isn’t necessarily easy but it is straightforward and obviously has to be done. But many research projects begin and end here, ignoring at least two things: that gap-filling research is probably what all of your competitors are doing right now; and the rest of this matrix of possibilities. Acknowledging that this is only one of four quadrants encourages us to look again at our research plan, at our assumed knowledge, and at our blind spots.

Rumsfeld talked about “known knowns”, the things that you know you know.

The known knowns

At the start of a project, team members will often share their knowledge, the material they have ready access to. This is important as they couldn’t be an effective team without sharing as much as possible. The risk is that this “known” knowledge never gets challenged, but do we really know it to be true? When was that knowledge created, under what conditions, is it still valid? What have we assumed? All organisations have their beliefs, rules of thumb that appear to simplify the world but which sometimes remain unchallenged for too long. Do they underpin our work, too?

Maybe the right research agenda will aim to examine and test the assumptions on which our brief is built. Testing and then reframing the core issue with users or expected users is fundamental to good design research: what is their take on the issue?; in what senses do they agree that something is a problem, and if not then what *are* their problems?

What we don’t know we know

We don’t have perfect recall; we forget that we know something until it gets called back to mind by some stimulus. It’s the same for teams, and also for organisations – most of the large organisations I’ve had the pleasure of working with have done something like this project before, it’s just that no one in your team either knows or remembers. In most large companies there’s always stuff that’s “known”, tacit knowledge, which →

eventually gets connected to the work we're doing. Often, its existence and relevance emerges as we discover other stuff. Or it may be the result of overlooking others within the organisation because they're not thought relevant to design, such as call centre staff, for example, who often have the richest and most direct contact with existing users.

One simple answer to this is to run the project 'openly', within the constraints of confidentiality. Make the project visible and accessible, maximise its surface area, publicise the project so that we increase the chances of the right people happening upon us and giving us ideas. This may seem too passive to be a research activity, but the problem with these lower two quadrants is that you don't know about this knowledge, so you don't know who to ask and what the right questions are.

What we don't know we don't know

If you accept the logic so far, then you have to acknowledge the presence of this last quadrant - that there is stuff out there waiting to be discovered that we simply don't know exists. If we don't know what it is, whether it exists or not, how can we ask questions about it? How do we even begin to organise research to illuminate it? And how do we begin to prioritise or cost this area of work when we don't know what it will contain or produce?

THE FIRST THING TO DO IS ADMIT THAT RESEARCH CAN FAIL

The first thing to do is admit that research can fail. Not everything you do will produce results and this can be quite a challenge to clients who equate design research with market research (a low risk summarisation (generally) of accessible data about a defined group). Design research is usually the amplification of weak signals in a noisy data set from an ill-defined group, so consequently high risk. Like most other forms of research within the design process, whether basic science research or testing prototypes, failure has to be accepted as the cost of success.

The second tactic is to 'abstract' the issue. In what way is the topic of our research possibly related to other topics that we do know something about? The relationship may be literal and close, or it may be functional, symbolic, metaphoric and tenuous; it is worth considering all options because, as you've already begun to acknowledge, we don't know the right places to look, and they're all good at this stage. I recall helping to design an implantable blood glucose sensor - a small piece of metal worn for long periods in the skin. To investigate this further I went to a piercing parlour and learned from the experience of the staff there where and how metal can best be tolerated.

When we don't know what to ask we have to leave ourselves open for the right questions to emerge and the third step helps with this - leave some white space, don't over-plan the research. Be honest - tell the client that you don't know what you'll do in the last few days of research (in practice, you never do anyway). But those last few activities will become obvious as you learn more, connect with more people, and challenge the orthodoxies; they're likely to be things you would never have predicted at the outset. Try to win the freedom to do these things as this is how you make discoveries.

I rarely tell people that Donald Rumsfeld helped me to do better design research, but he did. Without realising it, he gave me a tool to help me understand the research I know I have to do, and to highlight the research I could do. While your competitors - and you - are simply filling knowledge gaps, you also have three other areas of research to consider, three more ways to inform and inspire, and add significant value to the design project.



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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.

Therapeutic Hypothermia – catching your death of warm

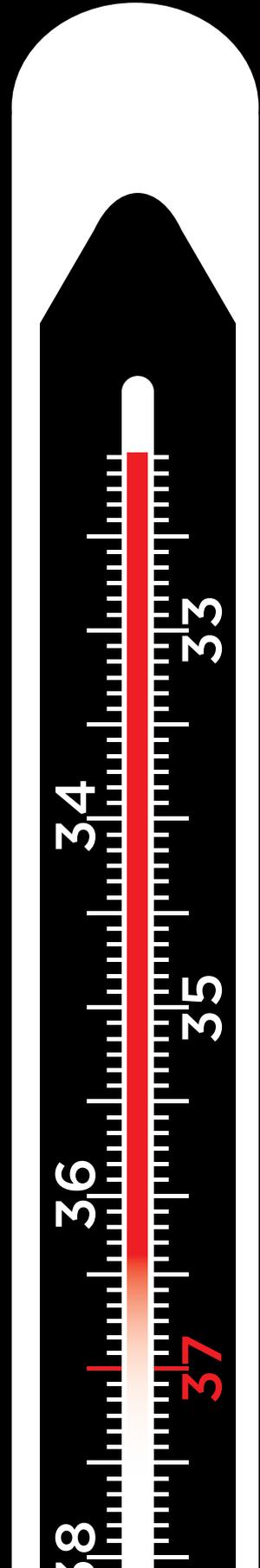
BY **BEN WICKS**

It's February, it's snowing and 56 year old Steve Grinstan has collapsed outside the delicatessen on the corner of 7th and 55th in New York suffering from a heart attack. The attending paramedics re-establish his normal heart rhythm within a few minutes, but Steve remains lying on the ground looking very cold. Next, the paramedics start infusing him with ice cold saline before putting him in the ambulance. The small group of bystanders stamp their feet in the cold and wander off discussing whether the unfortunate man may survive the heart attack, only to die of cold.

Strange as it may seem, the cold may actually help Steve make a full recovery. Over the last few years the deliberate use of therapeutic hypothermia in the treatment of heart attack and several

other acute conditions has become more and more widespread, and is now almost routine.

The use of hypothermia in medicine isn't a new idea. In the 4th Century BC Hippocrates described putting snow on an injured person, and the benefits of chilling patients was also tried during the Napoleonic wars. However, medical science embraced some fairly crazy ideas back then so it isn't surprising that proper investigation of therapeutic hypothermia didn't begin in earnest until the second half of the 20th century. Even then there were some fatalities because the clinicians got carried away and cooled people too much - only in the 1980s did clinicians begin to realise that cooling a patient by just a few degrees could have a significant benefit. →



How can cold be good?

Most of your body is designed to work optimally at 37°C. All of your cells and enzymes are geared up to do their work at this temperature. If your core temperature drops below 37°C then your physiology begins to slow down, your cells work more slowly, consume less energy and need less oxygen. This fact has been exploited for several decades to help protect the brain during heart transplant or cardiopulmonary bypass (CPB) surgery when blood flow to the brain is slowed and sometimes briefly stopped.

MOST OF YOUR BODY IS DESIGNED TO WORK OPTIMALLY AT 37°C

In 2002, two landmark clinical studies reported that mild hypothermia (cooling to 32-34°C) could improve the neurological outcomes of heart attack patients. Since then a great deal more clinical investigation has been carried out, and whilst there have been differences in the clinical protocols and measured outcomes, a picture is emerging which unequivocally shows that therapeutic hypothermia can improve survival and neurological function of heart attack patients. Direct brain injury can also be treated with therapeutic hypothermia, with several studies also strongly suggesting that cooling the brain can help prevent damage following traumatic brain injury. Interestingly, it's not just the brain which may benefit from being cooled. Preliminary evidence also suggests that cooling may even help protect the heart muscle itself which is starved of oxygen during a heart attack.

What does cooling actually do?

The influence of cooling on cellular and biochemical mechanisms within the brain is fairly complex.

All cells are normally regulated by a complex series of biochemical feedback systems which keep everything in balance within the cell (homeostasis). Damage caused by lack of oxygen can upset these mechanisms and can cause cells to spiral out of control and even push cells into a programmed self-destruct mode (known as apoptosis). Cooling helps to dampen the severity of these swings and reduces the risk of a cascade resulting in cell damage or death.

Nerve cells constantly send signals to one another by producing special chemicals known as neurotransmitters. When nerve cells are damaged they can give out toxic levels of these chemicals which can kill the transmitting cells and their neighbours; hypothermia helps reduce this level of neurotransmitter release.

How much chilling is helpful?

The clinical community is working hard to determine the optimum way to use therapeutic hypothermia, but as the process of clinical trialling is time consuming and difficult, there are as yet few hard and fast rules.

The first question is 'how quickly should cooling be initiated after the injury'?

This subject is hotly debated (sorry) but most people agree that cooling should start as early as possible after a heart attack or brain injury, and there is evidence that shows that it may still be worthwhile cooling a patient up to 12 hours after the injury or event.

The second question is 'how cold'?

Whilst cardiopulmonary bypass patients are sometimes cooled to temperatures as low as 15°C, it appears that cooling by only 3-5°C is probably sufficient for treatment after heart attack or brain injury. Even a few degrees of cooling has a significant effect, as brain metabolism decreases by around six percent for every one degree decrease in temperature below 37°C.

The last question is 'how long'?

Cooling is normally applied for 24

hours, sometimes longer. The process of rewarming the patient is usually controlled to make sure that it occurs gradually over a period of several hours, typically at 0.25 - 0.5°C per hour. Most of the cooling systems and devices on the market can be used to help rewarm the patient.

The science of cooling

We live in an age of amazing medical technology where we can see inside the brain using MRI, or visualise the beating heart of a baby in its mother's womb using ultrasound. The challenge of rapidly cooling a person by a few degrees therefore seems trivial – surely you'd think there was some kind of wireless technology which could be applied? Disappointingly, the physics of cooling is rather mundane and clunky, and you can't avoid the need to create a close physical coupling between the cooling system and the warm inside of the patient. You've just got to get the cold in and the heat out, and there's a lot of heat to get out. Cooling someone by 5°C requires the same dissipation of heat as cooling three kettles full of boiling water down to room temperature (~1700kJ or ~half a kilowatt hour).

One of the quickest and easiest ways of chilling someone is to infuse them with several litres of ice cold saline. This only cools the body by around half a degree, but it can be done quickly and is a good start. Many health providers are already advocating this intervention for heart attack treatment since it can be administered easily and requires little additional infrastructure, just a fridge in the ambulance.

Chilling out

Although you might think that it's very easy to get cold, the human body is amazingly good at keeping itself warm. A series of physiological systems make sure your core temperature doesn't vary significantly - shivering is an obvious example - and so it is quite difficult to quickly get someone cold. Despite its relative infancy, there are already therapeutic hypothermia products on the market and the medical device

industry has come up with some quite creative, and at times bizarre, methods to induce and maintain hypothermia.

Therapeutic hypothermia systems fall into three main categories:

- Extracorporeal (which cool the outside of the body)
- Natural orifice (yes, you've guessed it!)
- Intravascular (which cool from within the bloodstream)

Extracorporeal systems are the simplest, cheapest and most widespread. The normal format uses cold pads which are placed onto the patient's skin, and a refrigeration unit circulates cold water through the pads, with the most efficient pads having a gel coating to ensure maximal thermal conductivity between the coolant circuit and the skin.

The major disadvantages of extracorporeal systems are their limited cooling rate of $\sim 1.5^{\circ}\text{C}$ per hour, and the fact that a relatively large area of skin needs to be covered with the pads. The skin is quite a good insulation layer and vasoconstriction limits the amount of core blood which circulates near the skin.

Natural orifice systems, as the name suggests, use the body's orifices as a cooling interface (you're probably wincing as you read this). Theoretically, cooling should be quicker and more efficient since mucus membranes are thinner and less insulating than normal skin. Whilst almost all the imaginable orifices have been tried, the 'RhinoChill Intranasal Cooling System' deserves particular mention. Designed for out-of-hospital use on heart attack patients, the product squirts a rapidly evaporating coolant into the nasal cavity of the patient, cooling the blood and the nearby brain. If you get a headache eating ice-cream too quickly then you can imagine what the RhinoChill feels like! The product FAQ includes the incongruous question "What should be done if the patient's nose turns white?" As you might expect, there are practical

issues with almost all natural orifice systems and they are unlikely to capture much of the market without significant advances in usability and performance.

WHATEVER HAPPENS, THE FUTURE FOR THERAPEUTIC HYPOTHERMIA WITHIN EMERGENCY MEDICINE AND CRITICAL CARE SEEMS FAIRLY ASSURED

Intravascular systems use specially designed large-bore catheters which are inserted into the femoral vein. Cold saline is constantly circulated through the hollow catheter which, in turn, cools the blood. The catheter is sealed at one end so no coolant comes into contact with blood. The advantage of systems such as the Zoll Thermogard XP and Philips' InnerCool RTx is that they can achieve very high cooling rates in excess of 2°C per hour. The downside is that the procedure to insert a catheter is fairly invasive, carries some risks, requires a well-qualified clinician and in practice, the fast cooling rate may be offset by the time required to place the catheter.

Surface cooling, extracorporeal products seem likely to become the widely used technology but no one type of cooling technology is likely to dominate the entire market, and all three main types of cooling products are likely to find their own particular niche. There seems little chance that a pharmaceutical approach

(a 'chill pill') will ever be found which has the ability to influence the myriad of complex intracellular and extracellular mechanisms which can be dampened by simple cooling.

What's the future?

Expect to see more novel cooling products and technologies emerging in the next few years, particularly for the out-of-hospital / emergency care setting. Cold, breathable gas mixtures may have some potential in this regard. Mixtures of oxygen and inert gases with a higher thermal capacity than air have been explored for some time but some new approaches, including frozen mists, might make this approach feasible.

Whatever happens, the future for therapeutic hypothermia within emergency medicine and critical care seems fairly assured. The growing body of clinical evidence means that it will become adopted as standard for the treatment of heart attack and traumatic brain injury.



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Ben is Head of Critical Care and joined Team from Sagentia and Sphere Medical in 2012. His focus is on building on our success in this area.

Can you live without your phone?

BY BRENNAN MILES

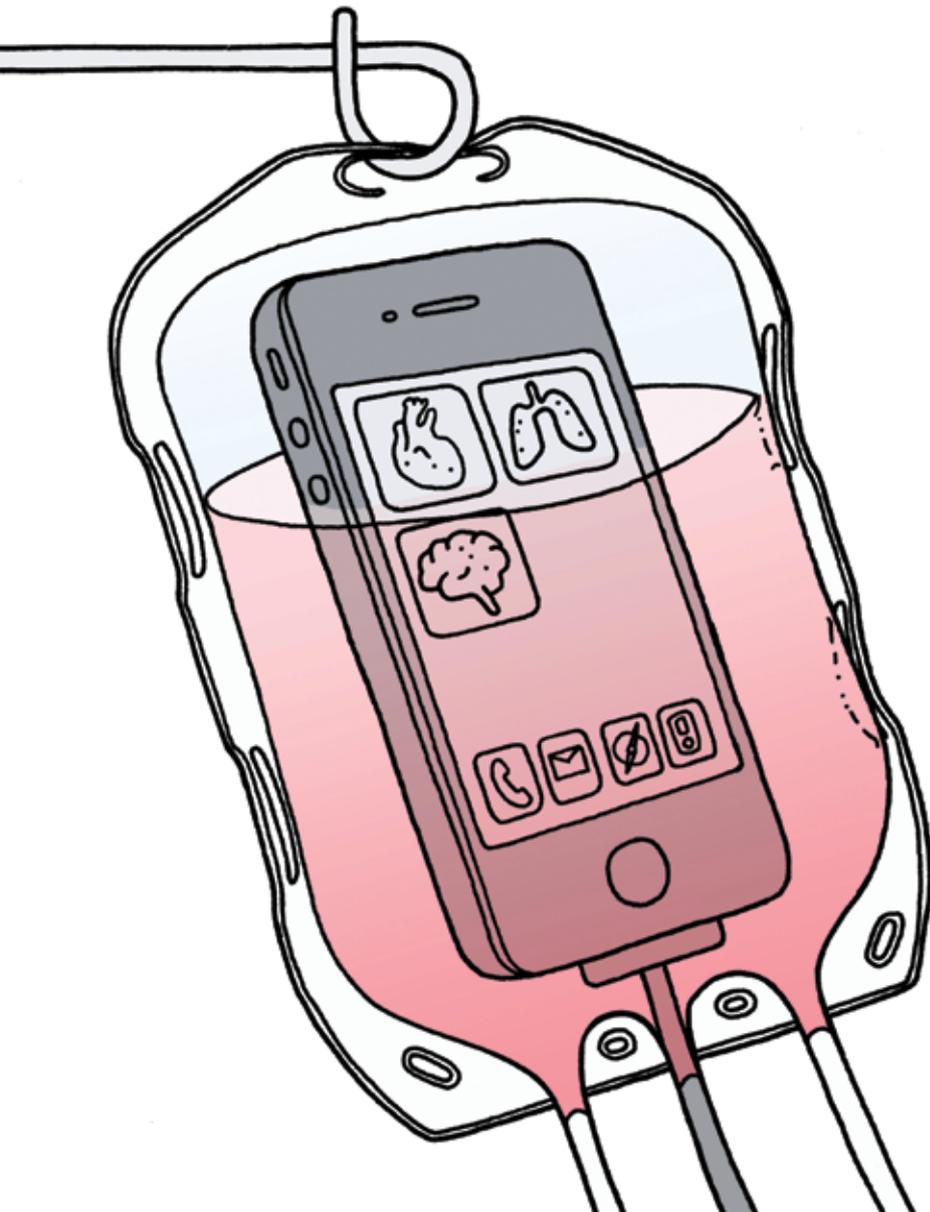
How often have you heard someone say that they 'couldn't live without their phone'? Surely it's just a bit of exaggeration, because they just really rely on their phone for work, or their social life?

After all, with a smartphone you can access the web, take (blurry) photos, play Angry Birds and occasionally check up on the odd work e-mail. But no matter how clever a smartphone is, it is not exactly essential for our mortal existence - but this could be about to change.

Mobile Health (or mHealth) is a broad topic but in general refers to the use of wireless devices - such as smartphones and tablet computers - to support health care and treatment regimes. But the aspect that is really interesting is the use of specially developed apps to convert any smartphone into a real medical device.

Some of these medical apps can enable a smartphone to carry out tasks such as remote health monitoring and care support, whilst others can communicate with add-on devices or peripherals to allow for more complex therapeutic tasks to be undertaken. These could include the diagnosis and treatment of chronic conditions, such as diabetes and asthma. The use of this combined technology is in its early stages, but it has a very real potential to radically change the way we approach standard healthcare in the future.

Manufacturers are making smartphones and tablet computers ever more adaptable with high resolution screens and longer battery lives. You can download games, music, e-books, web-TV and save all of the data (and blurry photos) to remote cloud servers. Mobile apps and these devices go hand-in-hand and we are increasingly using them for work, entertainment and for information - so why not also trust them with our health like any other medical device?



One good reason is that the companies who develop more standard medical devices such as inhalers and injector pens are closely regulated and follow strict directives and guidance. They carry out detailed risk analyses and verification testing to prove that the device is safe, and they undertake large validation studies in order to show that that the devices do what they are supposed to do. The problem is that the teams who develop mobile apps are not used to working to these sorts of standards. After all, if the battery dies during a game of Angry Birds what is the worst that can happen?

The risk of personal data security is also a big concern. Data sent wirelessly can be hard to protect and it's been well reported that some apps have hidden software that can read your text messages, and even track your location. It's pretty worrying to think that people could potentially have access to very intimate details on how sick you are. So this is precisely why the US FDA has stepped in to clarify the types of apps which will come under their authority - detailed in the FDA's draft guidance for Mobile Medical Applications, published in July 2011.

In most cases, this regulation does not apply to those 'Health and Lifestyle' apps which are mostly focused on tracking fitness or dieting, and account for around two per cent of the more than 650,000 apps available to download from Apple. Regulation only applies to those apps focused on diagnostics or those that tell you how and when to treat your medical conditions. The hope is that this regulation will not stifle the development of medical apps, but will provide credibility through the knowledge that the benefits and (most importantly) risks to public health have been considered.

As is the way with new technologies, this initial approach is interesting but cautious. Some examples of the first FDA approved apps include the Sanofi iBGStar blood glucose meter and the MIM Software Radiological image processing app.

In reality, not many fully approved apps have actually made it to the market yet. But there are some very good ideas under development which are not too far off such as a special electrode-studded case that turns the iPhone into a heart monitor that users hold in their hands or place on their chests to detect irregular heart rhythms. There is even an edible sensor that emits a tone when swallowed. The tone can be picked up on a patch worn on the outside of the body which then relays the sensor's data, along with heart rate and body movement of the patient, to a mobile phone for later analysis.

*You may think
that it's the intention
of mHealth tools to
take the place of
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not the case.*

You may think that it's the intention of mHealth tools to take the place of the GP but that is not the case, as the need for professional assessment and monitoring will always be an essential part of the healthcare process. Rather, the intention is for these technologies to support health professionals, by enabling more 'remote access care' (without the need to visit the surgery) to replace routine check ups and diagnoses.

It's easy to imagine that the apps that allow people to measure their own blood pressures and heart rates at home will also be able to communicate this data to a doctor, and this will lead to a considerable reduction in the number of home visits required for people with chronic conditions. As it's the nurses and caregivers that are generally responsible for these visits, they in turn will have more time to dedicate to the primary and palliative care of patients.

The potential for mHealth technologies to improve healthcare in developing countries is also huge not least because it is in these regions where mobile phone ownership is growing more rapidly than anywhere else. Although network speeds currently lag behind those found in developed markets, the use of remote diagnostics monitoring and treatment will undoubtedly help prevent sickness and save lives. Current developments specifically for these markets include an app for a phone-based E. Coli sensor for water and other fluids, which uses a lightweight attachment to the phone's camera to check the water quality. Commercial manufacture of this device could be only two years away, with the potential for many other similar apps to follow.

Remember how in the 'future-world' we learnt that doctors will always have a special machine to help them out? Well maybe mHealth is just that. Whether it is enabling better health management, diagnosis or just improving the patient experience, it's an exciting concept and it's only just getting started. So next time someone tells you that they can't live without their phone you may want to take them a bit more seriously!



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Brennan is a senior consultant and has worked on a range of surgical and drug delivery products including dry powder inhalers, injectors and ophthalmic devices.

Is India an opportunity or a threat to big pharma?

BY DAN FLICOS

On a recent trip to India, I was struck by the rate and scale of development I found there. The place has a vibrant and confident feel, which is not surprising given that it is one of the fastest growing economies in the world. The Indian pharmaceutical industry is seeing disproportionately high growth as it meets the needs of a rapidly expanding domestic market. But more than that, exports to both emerging economies and to so-called 'regulated' markets are also growing rapidly. This left me wondering whether India presents a net threat or a net opportunity to multinational pharmaceutical companies?

A large and growing market

According to PricewaterhouseCoopers, the domestic Indian pharma market is expected to grow at 15% to 20% CAGR (compound annual growth rate), reaching a value of between US\$50 billion and US\$74 billion by 2020. This is being fuelled by growth in the economy as a whole, an expanding population that is becoming more health-conscious, a government keen to promote health and wellbeing, and a rising standard of living. By 2040, India is predicted to be the most populated country on earth, overtaking China. India,

however, remains a very price-sensitive market; 67% of the population is in poorer, rural areas without good access to healthcare yet, disproportionately, this large segment currently accounts for only 17% of India's pharmaceutical market.

It is estimated that branded generics account for 90% of the domestic Indian market, with brand equity playing an important role in market share and pricing. As a consequence, a strong brand can still retain a reasonable market share and premium pricing, for some time at least. Conversely, newcomers to the market will struggle to compete against established brands and unless they can be cost competitive they will struggle in the market as a whole. We are therefore seeing more partnerships between multinationals and domestic businesses to mutual advantage, as Indian companies are in a strong position to exploit the domestic market either in their own right, or working with partners.

Exports are growing too

The India pharmaceutical industry has seen exports grow from almost zero in the mid 1990s to a value of about US\$12bn today. This is mainly in generics and APIs destined

for the US and European markets, and this growth will only continue as more drugs come off-patent and as western healthcare providers and insurers struggle to contain costs. Alongside these drugs, we will also see increasing exports of devices to be used in combination – particularly when devices come off patent. The Indian pharmaceutical industry also exports its services in the form of contract research and manufacturing, making use of a skilled and relatively low-cost work force and good facilities. As well as market-pull, the Indian government's special economic zones (SEZs) – where companies will be given free water, low-cost land and tax benefits – will encourage Indian companies to export more.

Challenges

However, the Indian pharmaceutical industry has been plagued by controversy and uncertainty in the area of IP law which, for years, has seemingly given an unfair advantage to the home team. India accepted the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) in 1995, yet problems remain. For example, in March 2012 the Indian patent office gave domestic company Natco Pharma the right to make and sell a version of Bayer's liver and kidney

BY 2040

India is predicted to be the most populated country on earth, overtaking china



= 100 Million people



U.S.A 383 MILLION



CHINA 1.36 BILLION



INDIA 1.63 BILLION

cancer drug Nexavar - despite the fact that Nexavar is still on patent. Whilst this sort of outcome is potentially good news for patients and domestic companies, the innovator companies stand to lose millions of dollars. As 90% of the market in India today is generics, growth in patented drugs is inevitable and will be needed in order to combat the rise in chronic conditions. Work is still required, therefore, to build confidence in patent laws among both domestic and global companies in order to see an increase in the number of new product launches.

In addition, Indian pharmaceutical companies have to acknowledge that what is acceptable in terms of quality and process for the domestic Indian market is not acceptable in regulated markets. Domestic companies looking to export drugs and devices will need to both understand what is required for each target market and then follow through with development and manufacturing processes that meet the required standards. This is perhaps most challenging when developing combination products (involving both a device and a formulation) for the US market, and presents a potential barrier for new market entrants. The potential rewards,

however, are large enough in many cases to make this investment worthwhile.

Although a potentially lucrative market, the growth in China is also a significant threat to the ambitions of the Indian pharmaceutical industry. It too is a major exporter of generics and APIs, offering similar services and benefits.

Perhaps the final challenge for India, and China for that matter, is that of sustaining current levels of growth and success. As their economies develop, the standard of living will also increase, as will the competition for talent. This will inevitably erode some of the cost advantages currently experienced, which is why many Indian companies are using today's revenues from generics to fund investments in new formulation and device developments.

So is India a threat or an opportunity?

Arguably the Indian market is a good opportunity that has not yet been fully seized by big pharma. According to an IMAP Global Industry Report, published in 2011, most global drug companies remain underexposed, and are underperforming, in the emerging markets. In 2009, the world's top

15 pharmaceutical manufacturers derived just 0.9% of their combined revenues from China, and 2.9% from the combined markets of Brazil, India and Russia - in many cases reflecting a continued focus on the premium section of the market rather than on the typically larger branded generics segment. Meanwhile the Indian pharmaceutical industry is ambitious, very much 'on the up' and looking over the shoulder of even the most established multinational.



— dan.flicos@team-consulting.com
Dan is the recently-appointed CEO, taking over from Jerry Turner who has become Chairman. Before joining us Dan held numerous positions at Sagentia, including Managing Director.

The role of an industrial designer has evolved significantly since I started practicing in the mid-90s, and looking ahead it seems like it will continue to evolve, not just because of the tools and processes at our disposal but also because of its changing role in medical product development.

What is industrial design? In reality, it means different things to different people - including designers themselves - as definitions are affected by where people are from and the industry sector they work in.

I've spent the last 10 years working purely on medical products, which require their own brand of industrial design, so my opinion is radically different from somebody who designs consumer electronics, but to give the debate some context, let's look at some history.

The origins of industrial design lie in the industrialisation of consumer products at the start of the last century. In Germany, the Deutscher Werkbund (a precursor to the Bauhaus) was a state-sponsored effort to integrate traditional crafts and industrial mass-production in order to put Germany on a competitive footing with England and the US. It was in the 50s and 60s, however, that the discipline became more prolific, with designers such as Raymond Loewy in the US and Dieter Rams in Germany helping to create products that many of us will still recognise today: from the Coca Cola bottle and the Greyhound bus to electric razors and home hi-fi for Braun.

The role of design continued to grow in significance in the US alongside the Silicon Valley technology boom. As functional products such as computers became more consumer-focused, desirability and usability became critical factors in their interface and aesthetics.

You can't really write an article about design without the A word appearing. But Apple, and in particular Jonathan Ive, have both highlighted the impact that good design can have on the success of a global brand. Many corporations are now following suit and moving towards a design-led strategy, mixing well-designed products with innovative technology and services to win over customers.

The medical industry has been behind the curve in integrating design thinking into the development process but it is catching up. This is largely due to the lack of market pull as end users are often not responsible for the purchase decision, instead being prescribed devices and medication by medical professionals who base decisions on a much broader set of criteria. Given their role in saving lives or making sick people feel better, priorities are understandably those of

“Design should not dominate people. It should help people”

Dieter Rams

Design's time to shine

BY PAUL GREENHALGH

safety and robustness. However, the role of design has become more important in the last few years since the FDA started to insist that evidence is provided on the usability of devices. This means that during the development process we at Team spend much of our time providing design solutions which meet the cognitive and physical abilities of users in order to ensure safety and compliance.

The industry is also starting to see the benefits of using design to reinforce positive brand messages through the visual language of devices, helping to communicate quality and the efficiency of the therapy provided. This, in turn, helps to build trust and an emotional connection between device and patient/user.

One sub-sector that is really embracing design is 'consumer medical' - products sold directly to the public to help them manage their own healthcare. As these products are selected by consumers other aspects need to be considered such as promoting feelings of trust and confidence, or making a device intuitive and easy to use with little or no training. As consumers become more involved in managing their health and the market becomes more competitive, I believe that pharmaceutical companies will need to take a similar approach. Wal-Mart recently announced that its UK supermarket chain ASDA will begin selling asthma inhalers over their pharmacy counters, which is a step closer to giving consumers choice in their medical devices. The importance of choice will also see us move away from the 'one size fits all' approach to one where core technology is packaged differently to appeal to different market segments. Such a move is not without its challenges, however, and designers will need to use all their creative skills to provide platform solutions which are commercially viable within a highly regulated environment.

So how else will industrial design evolve? At one end of the spectrum it's still about making things look appealing and 'adding value' through improved

aesthetics, ergonomics or novel features. But the role of an industrial designer is already extending beyond just the product itself. These days we're much more involved at the front-end, defining the user experience, the architecture of a product, and how the product fits within a client's service, brand or technology offering. Now, the physical interface is often not the biggest part of a product as graphical user interfaces (GUIs) play a key role in user interaction. So we'll stray towards information design, and design of the wider patient experience, embodied in apps, packaging and even instructions for use. The focus will be on creating a coherent experience from the first time a product is used to the point at which it is disposed of.

SO WITH THIS CROSSOVER THE ROLE OF THE DESIGNER HAS INEVITABLY BECOME MORE COMPLEX BUT ALSO MORE INFLUENTIAL

The evolution of new design, manufacturing and prototyping technologies has resulted in closer integration between designers and engineers. The two disciplines now work hand in hand and have developed a much higher level of understanding and respect for each other. This is in addition to the ergonomists and human factors specialists who work alongside designers to help ensure the right questions are asked in the right way in order to reveal un-met needs and to give designers evidence on which to

base decisions. So with this crossover the role of the designer has inevitably become more complex, but also more influential in the process.

I guess the way I look at industrial design is that our job is to ensure that user and client needs are understood, and then met through the experience that a product provides. It's as much about deciding what features to leave out as what to include.

Designers are the members of the team who lose sleep over the shape of button, and who obsess about creating a product that people can and want to use, and that fit with their lifestyle.

And even though most of our end users would, in truth, prefer not to have to use the device they've been prescribed or bought, if it can both improve their health and is enjoyable to use and own, then our work is done.



— paul.greenhalgh@team-consulting.com
Paul is Director of Design and has led the design or programme management of many products across drug delivery, surgical instruments, diagnostics, child-resistant packaging and consumer medical.



Sustainability in the Medical Devices Sector **What Does It Mean?**

TEAM DISCUSSION NO.1

‘Sustainability’ is a buzzword in almost every industry sector – but what about medical device design? What does it really mean in such a specialised and highly regulated context?

insight asked a group of Team consultants for their response to the issue of sustainability - where are we now, where are we going, and what does the future hold for our clients?



Taking part in the discussion

Paul Greenhalgh	Director of Design	PG
Chris Ferris	Head of Electronics and Software	CF
Stephen Augustyn	Head of Mechanical Engineering	SA
Ben Cox	Human Factors Consultant	BC
Colin Mathews	Chief Operating Officer	CM
Brennan Miles	Senior Consultant	BM

01

Easy to say but hard to define. What does sustainability mean for medical device design?

CM: The sustainability agenda is forcing companies in every sector to take a more holistic view of their activities; for medical devices, this not only means looking at the product itself – how it’s designed, the materials used and so on – but also at a much wider picture, from the energy required to manufacture the raw materials, to the impact of different logistical demands, such as cold chain storage, and then onto disposal.

PG: If we look at sustainability purely from the design perspective, a sustainable product needs to satisfy economic, ecological and social demands. It means that we can’t just consider short-term financial drivers when assessing a product’s potential. It will likely require the industry to focus on priorities other than those of safety, efficacy and robustness. It may even mean regulatory requirements being adjusted in order to promote sustainability.

CF: This is important, as a sustainable product must account for its ecological impact in terms of disposal and recycling – the wider picture mentioned by Colin - but these costs are not yet factored into development budgets or market pricing in our sector, making environmental impact always ‘someone else’s problem’.

SA: But all this is meaningless without the force of regulation. Sustainability is simply enlightened self-interest without legislation, or else considered a constraint making the pursuit of sustainability harder to justify in a highly competitive market place.

02

Is it the case, therefore, that sustainability is an issue that is not well understood in the medical devices sector?

BC: I think this is certainly the case – whereas sustainability is both ubiquitous, and a differentiator, for consumer products, it is not part of the design ‘mission’ for many of our clients. But sustainability is poorly understood by many end users as well – for example, there is a knee-jerk reaction against disposable products, but are recyclable alternatives really more sustainable, given the cleaning, sterilising and often re-engineering demanded? As the middle classes in the emerging economies continue to grow at a staggering rate, will this mix of awareness and misconception only increase and if so, is greater regulation coupled with greater education the answer?

CM: Top of the list for our clients is always safety and usability, followed by affordability which is, in turn, dictated by whoever pays for the product. Currently, these immediate goals outweigh longer term sustainability objectives. But the introduction of full product lifecycle analyses – already introduced in other sectors – could help challenge existing mind sets, and could eventually become a commercial driver as they provide a basis for performance comparison. Sustainability also demands a change to the corporate mind set in our sector, as it is a moral as well as a commercial issue, but it is also true that it is very difficult to assess the sustainability of medical products, as they can be so complex, and their use so specific.

CF: Widening the risk assessment process to include environmental impact could also play a part. This is relatively easy to do while a product is under development, but much harder once the product is out in the market place, and contributes to a poor understanding of the full impacts that medical devices could have. Perhaps, again, regulation could change this balance?

BM: One problem for our industry is that the ‘cost carrot’ that helps to encourage sustainable design in consumer products doesn’t always apply in the same way. For instance, by reducing the volume of raw material used in the manufacture of a kettle there are likely to be commercial benefits for both the manufacturer and the consumer. However, in the case of drug delivery devices it is difficult to apply the same rules because the costs of the drug can often far outweigh the costs of device manufacture, so there isn’t always a substantial commercial benefit to reducing the raw material.

03

Disposability – an obvious sustainability challenge – is clearly an important issue for the sector. What is the current state of play?

PG: A user has a very different relationship with a medical device than with a consumer brand, in that they exercise very little choice over what they are given. However, the general reaction to disposable products is undoubtedly negative, influenced directly by consumer product experience, and this is something we are increasingly aware of in feedback from interviews with patient groups when assessing new product concepts.

SA: There is also the growing issue of hospitals recycling ‘disposable’ products to save costs, with possibly life threatening results – such as the imperfect cleaning and then reuse of biopsy cutters. Single use devices are also sometimes pulled apart and then incorrectly reassembled, compounding the problem further.

BM: Disposable products are an interesting topic; even 30 years ago, most devices in a hospital were sterilised and reused whereas now, many of the same instruments are disposable. It is also interesting to note that previously, much more emphasis was placed on hospital ward cleanliness

whereas now we often read of high rates of superbugs on wards, such as MSRA. I’m convinced that an over-reliance on disposable items has partially led to a relaxation in basic cleaning skills – so going back to sustainable, re-usable products could have some huge benefits all round.

PG: It has to be said that disposable devices can offer greater patient safety, reducing risk of patient infection or transmission of dangerous diseases such as HIV/AIDS. However, disposable products have, by default, created a revenue model for suppliers which is difficult to change, even though users are now more focused on reducing cost and wastage. The lack of a direct feedback loop (end users are less often the buyer) also means that they have less overall influence on demand.

04

Looking further ahead, if sustainability drivers are currently weak, what will deliver the critical impetus for change?

PG: We all know that the commercial dynamic is different in the medical space, where regulation is so tight and where end users are, in general, not as brand aware or brand loyal – key factors in driving change through consumer sectors. But Governments are major purchasers of medical devices – they already demand more sustainable products, and this will hopefully encourage greater support from regulators, driving change through the sector.

BC: We’re already seeing the pressure Governments can bring to bear on suppliers in this context in other sectors – such as the recent refusal by San Francisco city officials to purchase Apple products as they failed to meet green guidelines for disassembly and recycling, a major embarrassment for Apple and one which prompted a corporate U-turn. Government purchasing power,

linked to sustainability standards, is very important and will start to shift some of the burden of product recycling onto the manufacturer.

SA: The influence of emerging economies – and their different approach to, and understanding of, medical devices – must also be closely watched as these economies already have drivers in common with a sustainable approach (such as an emphasis on recycling), and a more radical approach to cost cutting. Recent developments in single dose inhalers, destined for emerging economies where the cost of drugs is relatively high, feature stripped back yet elegant and effective designs comprising significantly fewer parts than the more complex inhalers being developed for Western markets. Perhaps we have something to learn from this approach?

BM: I agree with Steve; you can see the clear waste reduction benefit for a simple blister based inhaler of say six to seven components, over a more complex multi-dose inhaler (where the drug is contained internally) that consists of around 15 components. In a lot of cases, the simple inhalers can also be more efficient because of the shorter, simpler air-paths. As designers we need to ask; why are these types of devices not more popular?

CF: Overall, an increasing emphasis on sustainability will result in the realisation for manufacturers that they should assess both the cost of manufacture and the cost of disposal when calculating product development budgets, which could have a real impact on future product design direction.

05

Are there changes that medical device designers such as Team could be making now?

BC: There are some changes we could consider, even when not demanded by the client. For example, we could try to reduce the size of products where possible, as this has a direct impact on raw material use (and costs) and also on the supply chain, by reducing packaging for example, or transportation costs. Bigger innovations can also generate new IP opportunities for clients, which could be explored more actively.

PG: We could also provide a sustainability weighting when presenting product design options, as already happens in the development of big name consumer products. This could help improve general awareness of sustainability while also providing the information required to make an educated choice between product options. A limited form of environmental impact assessment could be part of this. The challenge will be to find enough 'good' information to base this assessment on.

CM: I agree. This is a major hurdle – being able to find and assemble enough reliable data to provide educated advice.

CF: We could explore easier sterilisation for certain medical devices wherever relevant and realistic – this would help address the disposability issue, provide a more sustainable approach, and challenge the market forces driving disposable options.

PG: The selection of new materials is an area we could also investigate more thoroughly. It's not as simple as just using glass instead of plastic; we need suppliers to provide better information about the overall 'environmental' cost. But we can also select grades of material which, due to their mechanical properties, can be used in smaller quantities. The big materials suppliers are starting to offer 'sustainable' grades of plastic, with assessment and information based on several key criteria, not just whether it's recycled. But given that we're already considering innovations such as the cardboard inhaler, we should look again at new materials when feasible.

SA: We already adopt design principles such as 'zero defects' and streamlined manufacture, strategies which meet sustainability goals of minimal waste, energy efficiency and so on. Perhaps a greater focus on these strategies as contributors to sustainability could help clients see the value of this approach?

06

Final thoughts?

CM: It's clear that our industry needs to understand how to better assess and address sustainability. This would allow us to see where and how we can contribute to the wider debate, and help our clients prepare for a future which is undoubtedly changing. For Team, taking a pre-compliance approach could be very valuable, and we can use our skills to identify new routes to sustainability which do not compromise product performance or market potential.

BM: Not that long ago we thought it would be impractical to separate our rubbish, we didn't think our clothes could be cleaned at 30°C and we thought the world would be dull without 60w incandescent light bulbs. But things have changed and the medical world also needs to keep up. We can look at the big changes such as fully recyclable cardboard inhalers and entire supply chain improvements, but this is a conservative industry and we shouldn't miss the simple opportunities, the continual step changes. These could include a resistance to 'over-engineering', specifying non-medical grade 'common' materials where the risks allow, and developing simple, recyclable packaging. After all, if you follow the Japanese Kaizen philosophy - small improvements lead to large results.

Information design for effective instructions

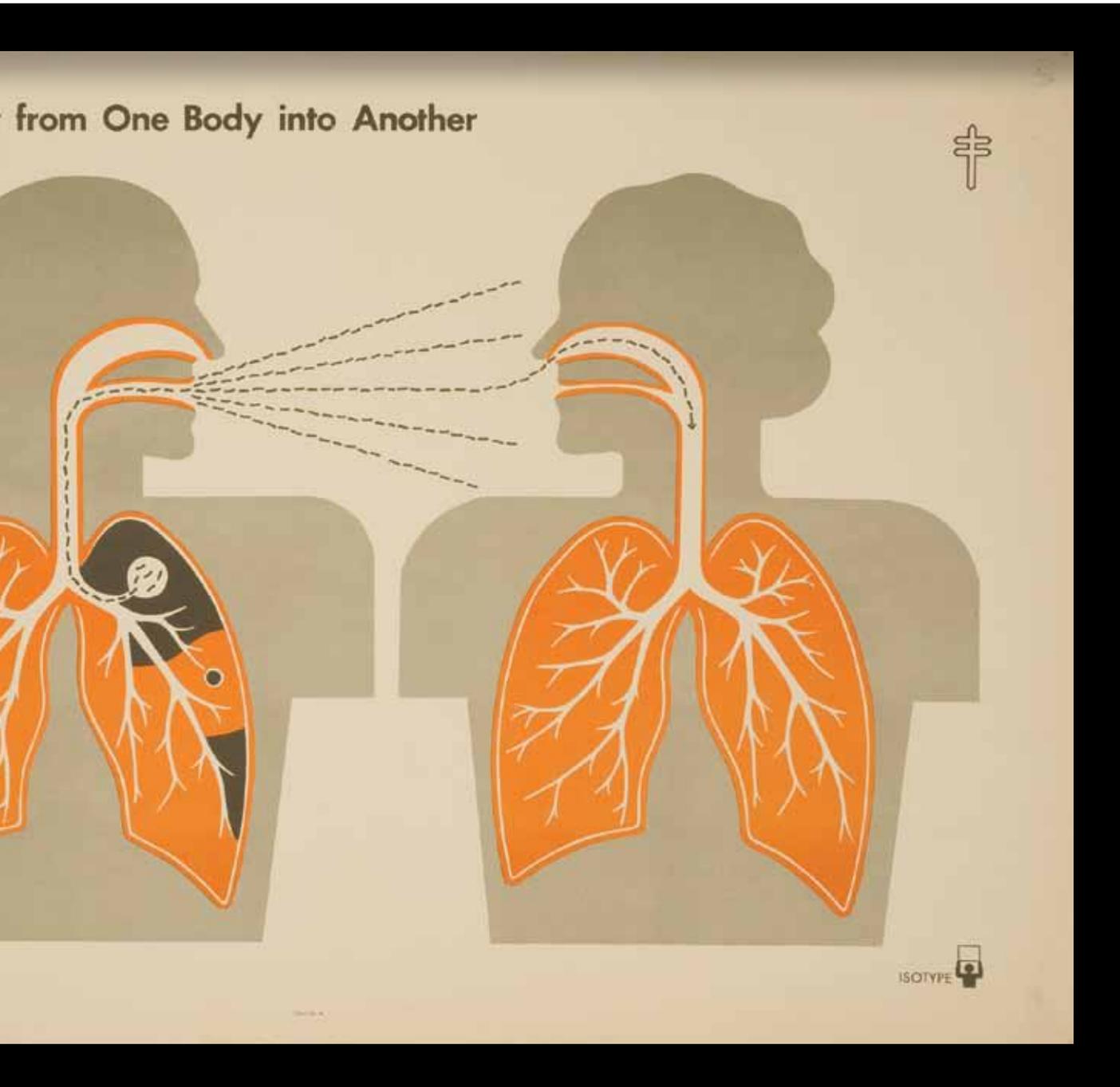
BY ALISON BLACK, UNIVERSITY OF READING

At the Centre for Information Design at the University of Reading we have a specialist team of researchers and designers who focus on the theory and practice of designing information that helps people 'get things done'. Our work is wide ranging, spanning a recent project to develop a checklist tool to help prisoners and officers avoid confrontations, to guidelines for the design of computer-based text and graphic materials for children.

The design of health information is a particular interest and we have some fascinating precedents to modern health communication in an archive of materials produced by the Isotype Institute in the 1940s and 50s (the Institute developed public information and education campaigns, including war effort posters and films for the UK Government in WW2).

Illustration 1 shows an Isotype poster, created for the American TB Association in the 1940s to explain TB infection and transmission. Although the work is a little dated, you can see many of the hallmarks of good information design: a limited amount of information per poster; titling to orient the reader; clear illustration combined with simple language; systematic use of a colour code throughout the campaign's posters; and strong cues to reading order.





The striking imagery used in the Isotype Institute's materials demonstrates awareness of the challenge of engaging and maintaining people's attention.

The striking imagery used in the Isotype Institute's materials demonstrates awareness of the challenge of engaging and maintaining people's attention. In one poster, diagrammatic illustration is combined with photographs to help connect technical presentation to people's everyday experience. For modern information designers there is often a tension between using realistic photographs and more focused, diagrammatic representations, which some people find difficult to understand.



What is clear, however, is that presenting information in different ways, including well written text and focused illustration, increases the accessibility of information. In a recent project to design a questionnaire to help the relatives of people with dementia inform nursing staff about a patient's symptoms, we made sure we used both verbal and graphic tools to maximise communication.

When it comes to reading instructions, research by Sullivan and Flower reveals that people rarely read two sentences of an instruction manual consecutively, often ignore introductory text and start using a product before finishing reading. Furthermore, the more familiar people feel with a product, the less likely they are to read instructions. (and most readers of this article will probably recognise their own behaviour here). But it is sometimes hard to imagine that a person using a medical product or device would not check the accompanying information first.

When a new medical product is developed, regulators require that accompanying information leaflets are tested for the accuracy and speed with which people can find information in them. These requirements focus on comprehension of leaflet text but research by Dickinson has shown that improving the design of typical patient information, such as the constructed leaflet for an imaginary medication 'Atenofen' shown in illustration 2, can improve performance on these tasks. That's a start. People respond positively to information that looks attractive and signals content clearly. But such tests only tell us a limited amount about people's every day experience of taking medicines and using medical devices. Often an individual has a regime of several interventions and relies on a mix of memory of the prescribing doctor's instructions, packaging inserts (if they read them), and, in the case of devices, cues from the design of the device itself. It's small wonder, therefore, that there can be slip ups in use.

So we have to look for innovative ways to engage people with the detail of how to use their medications and devices.

One way forward is to think of a coordinated information experience, from consultations with doctors (who are known to overestimate their patients' literacy levels), through interactions with pharmacists and family members, to access to web tools and mobile phone apps, and finally to packaging and information leaflets, and to the product itself.

The critical action at each stage is to tailor the information to user needs, engaging people but not overwhelming them. A rapid project by two of our undergraduate students (illustration 3) shows what can be done. They refined a lengthy explanation for school students about a new mobile phone-based service for contacting their school nurse, into an eye-catching poster and information card. While information designers have less freedom to 'play' with popular culture in patient information leaflets, experimenting with and testing alternative graphic forms to attract and focus readers' attention, to encourage them to keep reading and remember content afterwards, is key to design that helps people simply 'get things done'.



— a.black@reading.ac.uk
Professor Alison Black is Director of the Centre for Information Design Research, University of Reading. She is a psychologist by training but has always worked with designers in areas where design and research come together to meet people's needs.

Genetic engineers and molecular factories

BY **STEVE AUGUSTYN**

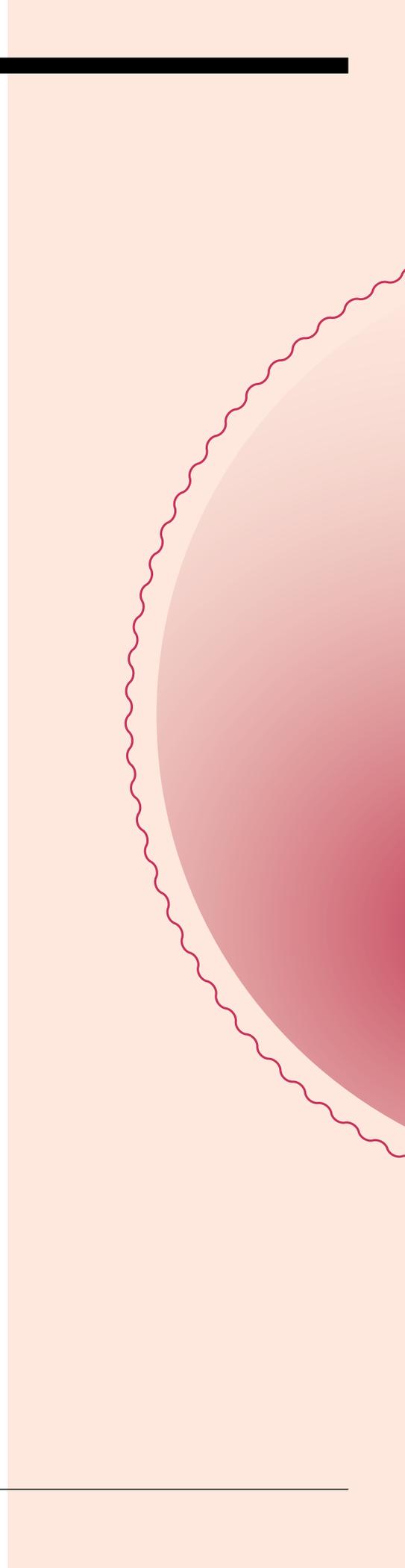
Regenerative medicine is one of the new frontiers in the development of medical procedures; using the body's own tissue and processes to repair damage and fight disease. Whilst there is some extremely exciting work being done in the area of tissue engineering and organ maintenance there is another field developing where the tiniest structures in the human body are being employed to return patients to health.

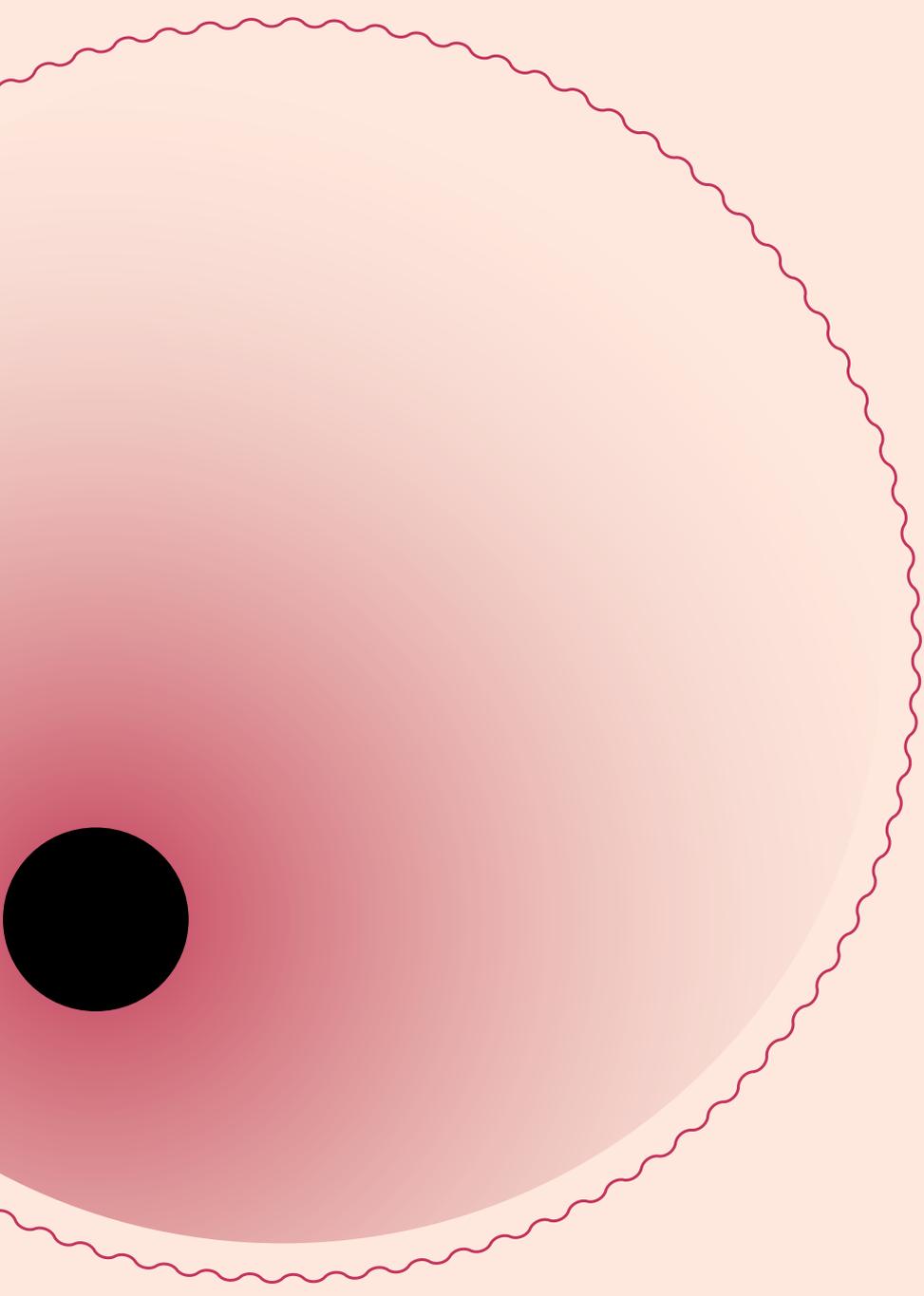
Gene therapy, as conceptualised in the early 1970s, is based on the use of genetically engineered DNA to treat disease. Whilst most current approaches to gene therapy rely upon replacing a mutated gene with a correctly functioning gene in the nucleus of a cell, there is another approach that can turn the cells of the body into miniature drug factories. Using an appropriately designed synthetic DNA it is possible but challenging to penetrate the outer membrane of a cell and transfect the cell nucleus. Once this has occurred, the biological processes in the cell will begin to replicate the DNA thereby expressing therapeutic protein that can be targeted to fight the disease that the patient is suffering from. This is the intent behind DNA vaccines.

The DNA molecule is delivered to the cell through the use of a vector, a biological unit that contains the key fragment of DNA required for protein expression and

a larger component that provides the structure of the molecule. Additional features of the vector can include components to encourage the expression of the gene and ensure that it attaches to the correct point on the host DNA. Delivering genetic material from one organism to another (a transgene) has been successfully, and commercially, developed for a number of applications including disease resistant crops, and the use of laboratory rodents to explore different human pathologies.

The key problem to producing cellular transfection is that cells don't really want alien material to pass through the cell boundary into the nucleus and have developed protective structures to prevent this. In response, viruses have developed approaches to pass through the cell wall and infect the cell nucleus and it is by attaching the desired section of synthetic DNA to a virus that a lot of the early success in genetic engineering has been achieved. However, even when the virus has been selected and modified to reduce any undesired issues, tying the gene for replication to a virus can produce unwanted side effects with active immune responses, cancerous mutation and toxicity. Even though the virus is deactivated when used in this way, there is still concern that the virus could mutate in an uncontrolled way and deliver a new disease to the patient.





Using 'naked' DNA in the form of plasmids is the other main way of delivering a synthetic DNA. A typical plasmid is a circular section of DNA that naturally occurs in bacteria. As with the virus vectors, a section of the bacterial plasmid DNA is removed and replaced with the gene, and with enough supporting material to enable replication, to complete the synthetic plasmid. Plasmids present several advantages over viral vectors as they can be produced in large scale and present fewer issues with immunogenicity. The biggest problem with plasmid vectors is persuading the target cell to transfect and commence production of the therapeutic proteins which will attack the disease the patient is suffering from.

The delivery mechanisms being explored rely upon introducing energy to the cells to disrupt the function of the lipid bilayer and allow the dna into the Cell nucleus.

If DNA plasmids are injected into tissue with a regular hypodermic needle the therapeutic response is so slight it can barely be measured and this resistance to transfection is largely down to the lipid bilayer. Found on the outside of a cell, the lipid bilayer is an extremely thin membrane of fatty molecules that controls the passage of material into and out of the cell.

Getting the modified plasmids past the lipid bilayer and into the cell nucleus is now the focus of much attention and the techniques being considered now require the skills of (or input from) the medical device designer. →

The delivery mechanisms being explored rely upon introducing energy to the cells to disrupt the function of the lipid bilayer and allow the DNA into the cell nucleus. There have been several approaches adopted including:

- **The Gene Gun** (or bioballistic) method; this uses small metal particles (usually gold or tungsten) which are coated with the desired DNA and fired into the target tissue.
- **Needle-free jet injectors**; these have been used to deliver vaccines to intramuscular and sub-cutaneous sites for years but the significant pressures that result can cause shearing of the DNA, tearing the plasmid into ineffective DNA fragments.
- **Sonoporation**; this relies on delivering ultrasonic energy to disrupt the cell membrane structure and improve take up of the DNA molecules.
- **Magnetofection**; magnetic nanoparticles coated with the DNA vectors are guided under directed magnetic fields to specific structures in the body.
- **Electroporation**; the most widely used way of improving DNA take up, this is the application of localised high voltage pulses produced by electrodes placed into muscle tissue.

Electroporation is used to improve the take up of cancer drugs. As these drugs can be highly toxic, the ability to target affected tumours with reduced dose quantities offers far better outcomes for patients.

In addition to this work on enhanced mechanical systems, one of our clients – Professor Matti Sallberg of ChronTech

Pharma - has developed a novel approach to injecting a synthetic DNA vaccine into muscle tissue. The IVIN (In Vivo Intracellular Injection) device uses an arrangement of multiple needles firing sideways against the line of injection to create a localised pressure increase.

The needles and injection ports are arranged in such a way that the DNA vaccine is directed into a central location producing a highly loaded area of muscle tissue that encourages the cells in the muscle to transfect with the DNA. In order to produce a consistent effect, the drug is delivered with the aid of a mechanical system that ensures the rapid delivery of the vaccine, independent of the healthcare professional's capabilities. The injection pressures are significantly lower than needle-free systems and examination of delivered vaccine shows little sign of strandification, suggesting that the shear forces are low enough not to cause problems for the DNA plasmids.

Team has been working with ChronTech Pharma to optimise the design of the needles and the assisted mechanical delivery device to produce the highest possible take up of the DNA vaccine.

Team has been working with ChronTech Pharma to optimise the design of the needles and the assisted mechanical delivery device to produce the highest possible take up of the DNA vaccine.

Early tests suggest that the IVIN system can significantly improve transfection compared with delivery with a standard hypodermic syringe. We are continuing to work with ChronTech to enhance this delivery even further and hope to have some very exciting news to report in the near future.

Breakthroughs in the design and creation of synthetic DNA vaccines present a paradigm shifting opportunity to treat some of the conditions which have proven stubbornly resistant to all conventional therapies. Whilst the understanding and control of the microbiology associated with DNA vaccines has advanced rapidly, efficient transfection of the vaccines into the host subject is fraught with complications. By combining cutting edge science and clever engineering there is finally hope for treating some of the most debilitating conditions and diseases which damage so many lives.



— steve.augustyn@team-consulting.com
Steve is Head of Mechanical Engineering at Team. Before he joined us he spent 11 years working with blue-chip companies in Europe, the US and Asia.

Events

DID YOU SEE US?

PDA Universe of Pre-filled Syringes
(October 2012, Las Vegas)
Team had a stand

Regener8 Annual Conference 2012
(September 2012, Newcastle)
Team were the headline sponsors and Stuart Kay gave a brief presentation

2nd World Pre-filled Syringes Summit
(September 2012, Washington)
Martin Bontoft and Julian Dixon ran a workshop on the future of self-injection. Julian also presented 'Appealing to users – developing usable and desirable devices'

The 39th Annual Meeting & Exposition of the Controlled Release Society
(July 2012, Quebec)
Andy Fry presented 'Parenteral drug delivery; the emerging device landscape and potential for the future'

Dry Powder Inhalers
(June 2012, London)
David Harris presented 'Beyond asthma and COPD: challenges and opportunities'

RDD 2012
(May 2012, Phoenix)
Colin Mathews led a panel session on human factors

Injectable Drug Delivery
(21-22 March 2012, London)
Andy Fry presented 'Are electronically enabled delivery devices (EEDDs) the future?'

DO YOU WANT TO MEET?

Parenterals
(November 2012, Barcelona)
Andy Pocock will be presenting 'Lowering the hurdles in device selection for biologics'

UniverCELL Conference
(November 2012, Cambridge)
Team is the lead sponsor for the emerging innovations stream

DDL23
(December 2012, Edinburgh)
Paul Greenhalgh will be speaking on 'Challenging the barriers to consumer choice'

Pharmapack 2013
(January 2013, Paris)
Team will have a stand

5th European Pre-filled Syringes
(January 2013, London)
Julian Dixon and Martin Bontoft will be running a workshop on self-injection.

DID YOU READ?

- **EMDT, November 2012**
Steve Augustyn on DFx and its benefit over DFMA
- **Regen, September 2012**
Stuart Kay on why too early is better than too late in product development
- **Inhalation, July 2012**
David Harris on the technical challenges of designing a DPI
- **Therapeutic Delivery, July 2012**
Andy Fry on electronically enabled delivery devices (EEDDs)
- **Journal of Diabetes Science and Technology, June 2012**
Andy Fry on future injection technologies
- **New Electronics, February 2012**
Chris Ferris on how power management is becoming a growing challenge
- **EMDT, November 2011**
Philip Canner on the unique challenges of fluid handling

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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