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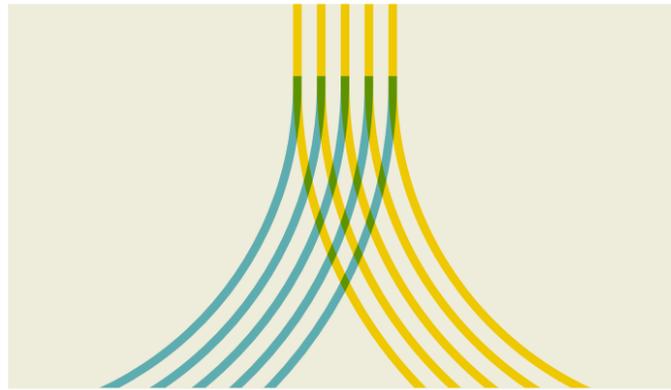
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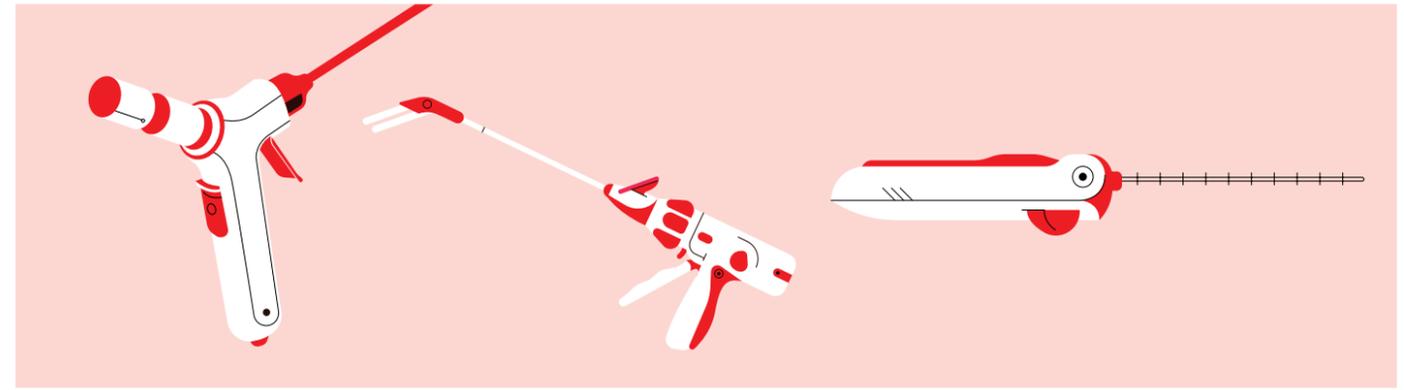


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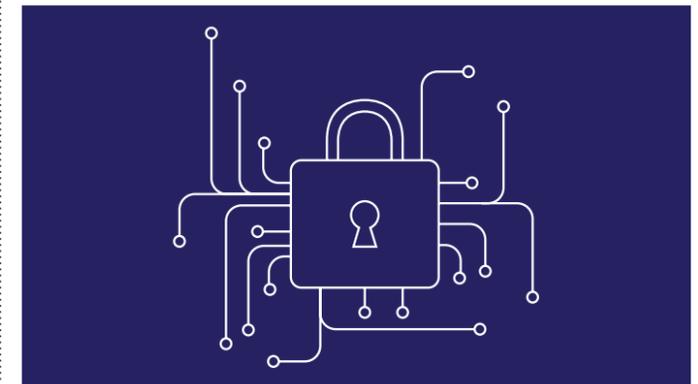


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By Mark Emery



Complexity and collaboration

What used to be considered science fiction has become science fact within the span of a single lifetime. Those of us of a certain age will remember “The Six Million Dollar Man” and now bionics is a reality. The complexity of modern medical devices requires great teamwork to meet increased levels of performance and visionary ambition for better products.

In this issue of *Insight* Nia Stevens describes some of the many challenges involved in developing an inhaler and Ben Wicks looks at the complexities of connecting devices to the human brain. Both require a truly multi-disciplinary approach, combining expert knowledge of the human body with expertise in science and engineering. Complexity comes in many forms and not to be overlooked is the usability of devices – we reflect on the 20-year growth of our Human Factors team. Cybersecurity is a growing issue and Mark Emery offers some practical advice as to how to mitigate this threat when developing medical devices. Complexity can also come from a combination of market and regulatory drivers – Iain Ansell suggests that there are 10 factors holding back innovation in surgical devices. By matching some of the latest thinking in innovation process to the peculiarities of the medical sector, Charlotte Harris explains how we are using Design Sprints to create and test ideas quickly. Finally, Andrea Pybus reveals all about how to build the perfect team to deliver your next project!

I hope you enjoy reading your copy of *Insight* and that we provide some food for thought.



Dan Flicos, CEO



Team's *Regulatory Handbook* is available, get in touch to request your copy: info@team-consulting.com

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Designed by
Studio Parallel



Nia Stevens

Consultant Mechanical Engineer

Nia applies her extensive experience developing and applying math models within the pharmaceutical industry to a variety of client projects at Team. She is a Chartered Mechanical Engineer and also completed a GSK-sponsored PhD in modelling Dry Powder Inhaler flow.



Julian Dixon

Director of Human Factors

Since our first significant user research project in 1999, Julian has been core to the development of our human factors capability. He also takes an active role in understanding emerging FDA expectations with regard to human factors.



Mark Emery

Medical Software Consultant

Mark focuses on embedded software development for large multi-disciplinary projects, breaking down complexity into a managed project.



Diane Aston-James

Head of Human Factors

Diane is responsible for the management, planning and implementation of formative and summative research studies both directly for Team's clients and as part of Team's product development process.

“I'd rather regret the things I've done than regret the things I haven't done.”

Lucille Ball



Ben Wicks

Head of MedTech

Ben drives the MedTech business at Team. He brings first-hand knowledge of a wide breadth of science and engineering used to enable sensing and actuation in diagnostic and therapeutic products.



Iain Ansell

Head of Surgical

Iain has over 30 years of experience in developing products where his skills range from the strategic to the technical and practical. His surgical device development projects include: energy devices, single-use, reusable and complex surgical robotics systems.



Charlotte Harris

Head of Front End Innovation

Charlotte helps clients set off on the right path in the early stages of product development. She is an experienced project manager and facilitator, guiding clients through both difficult strategic decisions and encouraging creative thinking.



Andrea Pybus

HR Director

Andrea offers a mix of strategic and operational HR within Team. She works in partnership with the management team to drive forward growth and staff development.

Design Sprints: rapid innovation in a regulated world

Implementing Design Sprints in early stage medical device development

By Charlotte Harris



Start
100m

“The aim of a Design Sprint is to create and test ideas quickly, so if you’re going to fail – you fail fast and fail early.”

You may have heard of the term ‘Design Sprint’ – an increasingly popular process developed by Google Ventures (GV) where a team work together in a fast paced way to answer critical business questions through design, prototyping, and testing ideas with customers in just 5 consecutive days. At Team we’ve been running Design Sprints for a while now as part of our front end innovation process and have learnt some valuable lessons on what makes the tool more effective in our field of medical device development. We thought we’d share our experiences and the hybrid sprint process that we’ve developed.

The Design Sprint Process

The ‘official’ GV Design Sprint is a five day process. It starts on a Monday taking the team through a day by day journey where by Friday you’ve understood the problem, created promising solutions, chosen a frontrunner, built a realistic prototype and tested it with users.

The aim of a Design Sprint is to create and test ideas quickly, so if you’re going to fail, you fail fast and fail early. You move through the process rapidly so you make decisions quickly and avoid getting too wedded to early ideas. Prototypes are low fidelity – something that can be made in a day – with enough functionality to get early feedback from stakeholders. Ultimately, whatever you learn from your user testing on the Friday, you’ll have uncovered an enormous amount of information helping to steer next steps.

Sprinting at Team

Since we’ve been using this innovation tool (and in the true spirit of innovation) we’ve experimented with a few approaches. We’ve followed the five-day Design Sprint process to the rule book as well as adapting the process for longer with two, three and four week sprints. We’ve also conducted multiple 2-3 week sprints consecutively as part of a larger innovation programme which has enabled us to rapidly parallel track a number of early ideas, working very closely with our clients. We’ve learnt that a 5-day Design Sprint isn’t always the answer and that some challenges and clients benefit from a slightly longer sprint to address prototyping challenges, source materials or fit with our ‘remote’ clients’ travel schedules.

Each time we run a sprint, we adapt the process, taking elements from the 5-day version and tailoring them to the specific challenge and client at hand. Sometimes the exploration of the problems varies in length, sometimes it’s the idea creation phase and other times it’s the prototyping or testing phase that’s longer.

But each time we’ve evolved what we’ve done and this experience has enabled us to tune what works for us in a medical device consulting environment and work out how we can best help our variety of clients with product innovation – quickly!!

What follows are 7 key learnings we gained from running sprints and how we have adapted the process. →

Start
200m

1

The right 'sprint' environment (for the duration) is key

Having the right creative environment for a sprint is essential. First it needs to be a space where the group can lock themselves away, undisturbed for days at a time. It needs to be somewhere you can stick things up on the walls to help you map out your problem, create, display, explore ideas and move through the Design Sprint journey without having to change rooms or take stuff down at the end of each day.

We have found that keeping the same space for the duration of your sprint(s) is key – so you have the information, stimulus and ideas all around you, all the time. So we've created a dedicated sprint room with cork walls, write on walls, AV equipment and a lifetime supply of different coloured and sized post-it notes, white-tack and sharpies. We redecorate the room each day with creative and strategic output from the sprint. It becomes a physical manifestation of the inner working of the group's mind – a 3D mindmap if you like. This serves as an accurate capture of the project progress and is far more powerful than any slide deck. It is particularly useful if we are joined by clients for co-creation sessions, as it cuts down on presentation time and enables members of the broader team to immerse themselves quickly.

Knapp, Zeratsky and Kowitz wrote the book *Sprint: How to Solve Big Problems and Test New Ideas in Just Five Days* about their work at Google Ventures.

Start
400m

Finish
100m

“For a successful Design Sprint you need the right mix of the right people with the right knowledge and skills and the right open mindset.”

2

You need the right brains in the room at the right time

For a successful Design Sprint you need the right mix of people with the right knowledge and skills and the right open mindset – right! These are most likely a mix of our client's commercial and R&D teams working collaboratively with Team's design, engineering and human factors specialists who love solving a good problem and who can think quickly, laterally and diversely.

Although everyone isn't necessarily needed for all 5 days of a Design Sprint, the core team does need to commit. The client team and other Team specialists are needed for at least the first 1-3 days where the bulk of the creative and selection work happens. But finding 3-5 consecutive days when all these people are available can present some real scheduling challenges for the sprint process.

To help with this we've either condensed some of the sprint days or had a day or two off in between so that we can get the right people available. By being flexible with the activities and/or spreading the sprint over a couple of weeks instead of one, it's not quite so demanding on the participants and just makes life a bit easier to manage.

But as if scheduling people for a sprint in the first place isn't enough of a challenge, keeping busy people from being distracted by their important day jobs once the sprint has started is another challenge. To minimise distractions, we use the dedicated 'sprint' room mentioned above and we encourage sprint participants to switch off phones and laptops during the intense creative days, ensuring we schedule lots of coffee breaks and go offsite for lunch to re-energise and check emails.

3

It's crazy and intense – but you've just got to go with it!

I can't lie, participating in a Design Sprint is intense. It's fast paced and requires dedicated brain power for ~6 hours a day. It can seem a bit crazy and uncomfortable at first, as it's a move away from traditional working practices, but it can be great fun and immensely rewarding as you see things happening so fast.

This all steps up a notch for the facilitator who has to guide everyone through the process and keep track of time. We've found it really beneficial to read the book as it lays out what happens each day and what is needed. But it still requires a good facilitator to be on top of everything, to be energetic and highly organised, to ask questions to get information out in the open, to make sure you and others write that information down properly, and to mind the clock and move through the steps. It's intense and takes practice – so we had to get comfortable with the published process before being able to work out how we could tailor it for our needs.

4

You need a well-defined (right!) problem before you start sprinting

The point of day 1 of the sprint is to define the problem and the question(s) we are trying to answer in the 5 days. It is critical to be able to clearly outline the user, technical, and business requirements. But sometimes the problem just isn't that well defined, there are gaps in the groups' knowledge and more research is needed to inform the requirements before we get sprinting. That could take the form of an upfront strategic requirements gathering workshop, or it could be a piece of design research with end users, competitor device landscaping or technology scouting for example. Whatever form it takes, we've found that an intensive sprint process just doesn't work well without having a very clear problem defined on the first day. This prevents you heading off down the wrong track with your sprint. →

5

Sometimes you just can't prototype something in a day

The 5-day sprint process developed by GV is best suited to digital or consumer products where prototyping times are a little quicker. It allows just 1 day for building the prototype (day 4). If it's a digital solution or a simple interaction you want to test then that's long enough to mock up a few fake app screens in Invision, or create prototypes in cardboard, foam or a basic 3D print. But in our medical device world we often want to test more complex interactions which demand more complex physical prototypes to be able to answer the questions we have. The fact is, sometimes a day just isn't long enough to even design and build some useful low fidelity prototypes and we need a bit more time.

We've realised that if you want to create the sorts of physical prototypes we need to test with users, then you need at least a 2 week sprint. The first week to do the creative part of the sprint process and the second week to create, fettle, build the prototypes and test them. What's important though is that you don't use it as an excuse to drag out the process and lose the benefit of rapid-fire development – so our advice is that you only build in the extra time that you REALLY need.

“Sometimes a day just isn't long enough even to design and build some useful low fidelity prototypes and we need a bit more time.”

6

Recruiting real end users to test medical device product ideas isn't straightforward

At Team we only develop medical devices, so our end users are primarily patients, carers and health care professionals. This can sometimes present challenges with the testing which should occur on day 5 (Friday) of the Design Sprint process. Unlike consumer products where almost anyone could be called upon for the testing, end users for a medical device might be very unwell or hard to access. Finding and recruiting people often takes longer than the few days the sprint process allows.

Firstly, we'll consider whether we need to see the actual end user or can we find out answers to questions we want by testing with healthy volunteers of the same demographic who we can find more easily (friends, family and colleagues can be a valuable resource). But if we do need to speak to a handful of real end users, we typically need 1-3 weeks to recruit, meaning a delay to the scheduled sprint process. To ensure this happens as efficiently as possible we need to initiate recruiting as soon as we know our target users. If we know who they are before the sprint starts, then we can line them up earlier and hopefully for the 5th day.

If we are only able to identify the target users at the start of the sprint, then the time gets added on at the end. To help with this we've formed some links with local hospitals and recruitments agencies to help us get quick access to small numbers of patients and professionals nearby.

7

It's OK to not know what's happening from one day/week/fortnight to the next!

Working in an Agile way where multiple design sprints happen one after the other or where design sprints turn into fortnightly Agile development sprints, requires a different mindset than we may be used to in a typical product development process. Not everyone will be comfortable working in this way – those who are more used to having a defined set of requirements at the outset and following a set linear process may struggle to adjust – so a lot of encouragement and reflection on what is being achieved is required from the facilitator. We have found that if the team has an open mindset then it's easier to adjust to this way of working where you are finding things out as you go along and where you don't know what's happening from one day to the next.

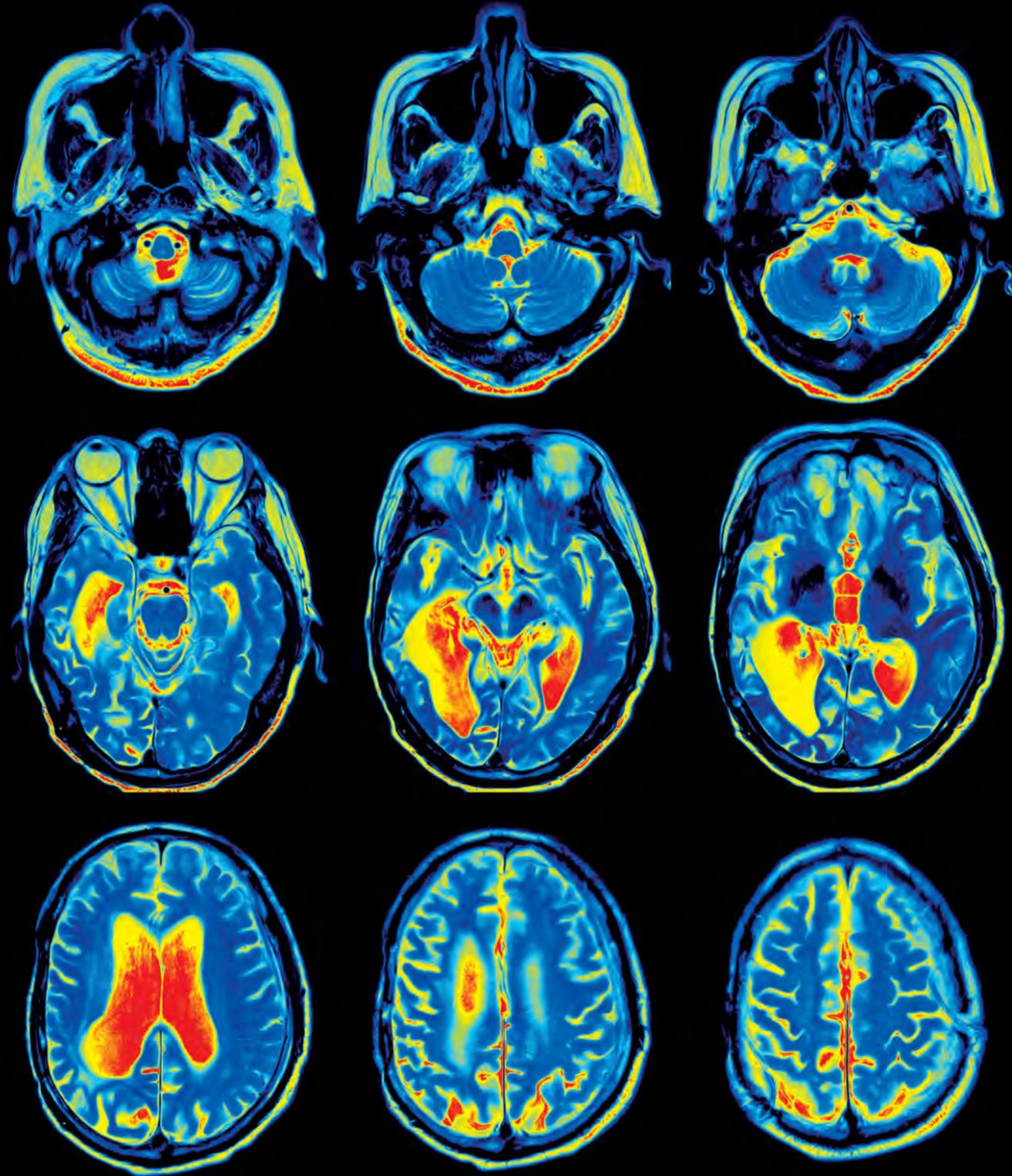
The front end innovation process can be fairly haphazard and ill-defined at the start and gradually becomes more focused as more information becomes available and a direction can be agreed. The same needs to happen with the focus of the sprints. As you undertake several in a row and more information is learned in each, then the focus becomes clearer and the sprint activities need to adapt and change as this happens. You just need to trust in the process!

In conclusion, I could imagine the documented 5-day Sprint process works really well for fast moving consumer products and digital solutions where it's easy to mock up prototypes and get access to users for testing.

That doesn't mean that we can't use the outline process and elements of it to be more efficient and collaborative in a slower moving, more regulated industry such as the medical device world. It just means it needs adapting slightly to address some of the challenges outlined above – and we're working on that. As we do more and more sprints we will continue to evolve and tailor the way it works for our clients, works for us and the specific problem at hand. It's a different way of working that gets results quicker, means failures occur earlier and prevents going off on the wrong path leading to costly failures later in development. So it can only be worth strapping yourself in and going along for the ride! ENDS

“We have found that if the team has an open mindset then it's easier to adjust to this way of working where you are finding things out as you go along and where you don't know what's happening from one day to the next.”

Start
300m



The connected brain

Nerve cells don't speak electricity

By Ben Wicks



As far back as 1875 scientists have recognised that electrical activity takes place in the brain. Over the proceeding 145 years more and more research has shed light on the role that electrical signals play in the nervous system and the brain.

From early on it was recognised that the electrical activities within the brain and nervous system can be measured, and conversely electrical stimuli can be applied to the brain and nervous system to make it do things. →

Research in this field is increasing exponentially – advances in neurobiology mean we understand more than ever before how nerve cells work and how signals are transmitted. Advances in microelectronics and the recent explosion in digital connectivity has created countless opportunities to make electrical connections with the brain. Some of the more prominent applications are deep brain stimulation to treat Parkinson's Disease, sight restoration systems using simple cameras and re-establishment of motor control to spinal cord injury patients.

The term 'brain-computer interfaces' has been coined to describe this exciting new area; 'neuroprosthetics' is also another buzzword. Such restorative treatments are potentially quite astonishing, but since each piece of new research is described as 'groundbreaking' it's difficult to distinguish the real breakthroughs from reworking existing technology with a small twist to generate publicity.

“Whilst neurons don't conduct any electrical current, electrical signals are involved in passing messages along nerve pathways.”

The purpose of this article is to seek to shed light on the really important breakthroughs required to allow us to connect with the brain and realise lots of wonderful things. We will look at three essential challenges to consider. Firstly, that the interface between the electronics and nerve cells is the biggest fundamental challenge. Secondly, a truly multidisciplinary approach is essential to translate clever science into impactful treatments. Finally, that academic research teams must grapple with the regulatory challenges at the earliest possible opportunity. In the following sections we will unpack each of these in more detail, before concluding with what we might expect to see reach the market in the next 5 years.

Electronics and nerve cell interface

Nerve cells don't speak electricity – unlike the entire digital world which converses in volts, amps and bits. Uniting these two different worlds is the single most fundamental challenge in creating brain computer interfaces.

Whilst neurons don't conduct any electrical current, electrical signals are involved in passing messages along nerve pathways. However, electrical signals can be delivered to nerve cells which then pass on the message. Conversely, it's possible to measure the tiny electrical signals from nerve signals. In either case a conductive electrode needs to be poked into the brain or placed near the nerves. This is normally a piece of metal, for example cardiac pacemakers have metal tipped electrodes, but other conductive materials such as polymers are increasingly being used. It is possible to do some of this remotely through the skin (for example an ECG measures cardiac signals through the skin and an external defibrillator sends an electrical signal through the skin to the heart) but to get well connected to the brain it's necessary to get close and intimate with the neurons themselves.

There are some very real problems with poking bits of metal into the brain. Even using fancy alloys (typically platinum-iridium), the wires can be seen as foreign by the immune system and encased in scar tissue leading to fouling or encapsulation, which prevents good transmission of the electrical signals. An even bigger challenge is increasing the resolution of connections into the brain – making a larger number of electrical connections to smaller, discrete three-dimensional areas of the brain. In the early days researchers were satisfied placing a few electrodes into different parts of the brain, but as the science moves forward there is a demand to make larger and larger number of connections to obtain greater and greater precision. This throws up two problems. The first is how to fabricate such complex arrays, though modern fabrication techniques (such as additive manufacturing technologies) enable quite complex

Passing signals in the brain

Neurons are cells that pass the signals in the brain. Depending on their connections and shape they can carry out different functions such as controlling muscles or storing memories. Neurons carry messages in the form of electrical signals called nerve impulses. Each neuron is made of a cell, body, dendrites and axon. Axon and dendrites are the parts of the neurons which send and receive messages. Each has branches which are very close to other neurons, but they don't touch. This area of "closeness" is called a synapse. At the synapse the information jumps from the axon to the dendrites via neurotransmitters, carrying the electrical impulse to the next axon. Axons carry the electrical impulses.

structures to be created. The second and more intractable problem is how to place a 3D electrode array into the brain without severely damaging the bit of brain you're interested in. Even if a complex three dimensional array of electrodes can be put into place, the wires connecting each electrode have to go somewhere and will inevitably cause some physical disruption to the brain tissues which they pass through.

Some clever work is being done to better integrate microelectronics with neurons. For example, the UK start-up Neuroloom is using microfabrication techniques to create an array of tiny, hollow needles, into which nerve cells can be grown. It is hoped that this will help create higher resolution interfaces in which the nerve cells are closely coupled to a conductive support structure, thereby improving the electrical coupling between the electronics and the cells. This field is in its infancy, but it seems plausible that 'collaborating' with neurons is likely to yield better results in the long term than simply forcing them into close proximity with foreign structures.



Multidisciplinary approach

Neuroloom is a good example of multiple disciplines (in this case microfabrication, cell biology and micro-electronics) working collaboratively to solve the challenges of interfacing with the brain. Connecting microelectronics to the brain and making products which can advance science and help patients is an inherently multidisciplinary subject. It requires input from experts in the fields of physiology, cell biology, electronics, computing, user interface design and mechanics.

We've already discussed the electronic-neural interface, but deep understanding of many other fields must also be brought to bear. For example, the microelectronics often need to detect the most faint of electrical signals against a background of other 'noise'. The electrical systems often need to be miniaturised and designed to reduce power consumption; inductive powering and communication through the skin may also be required.

All successful therapeutic products need a well thought through user interface / physical interface, but sadly this aspect is often overlooked because the

emphasis is on the clever science. It is essential to bring these skills into the multidisciplinary team. Investment in design research, human factors testing and consideration of the user interaction is always a good investment for any medical device, not least something which is connected to the brain.

Signal processing is a core aspect of interpreting neurological activity; much has been published in this field, but it still requires in-depth knowledge to select appropriate algorithms which can be verified and validated to satisfy the requirements of regulators. This is an area in which an understanding of medical device regulation and development of medical software is utterly essential. It isn't uncommon for research groups to demonstrate proof-of-principle in the clinic using bespoke signals processing algorithms, only to have to rewrite the software with the required sufficient rigour, documentation and quality management to be acceptable to regulatory bodies. Again, the advice is to bring together the range of required disciplines earlier rather than later in the process.

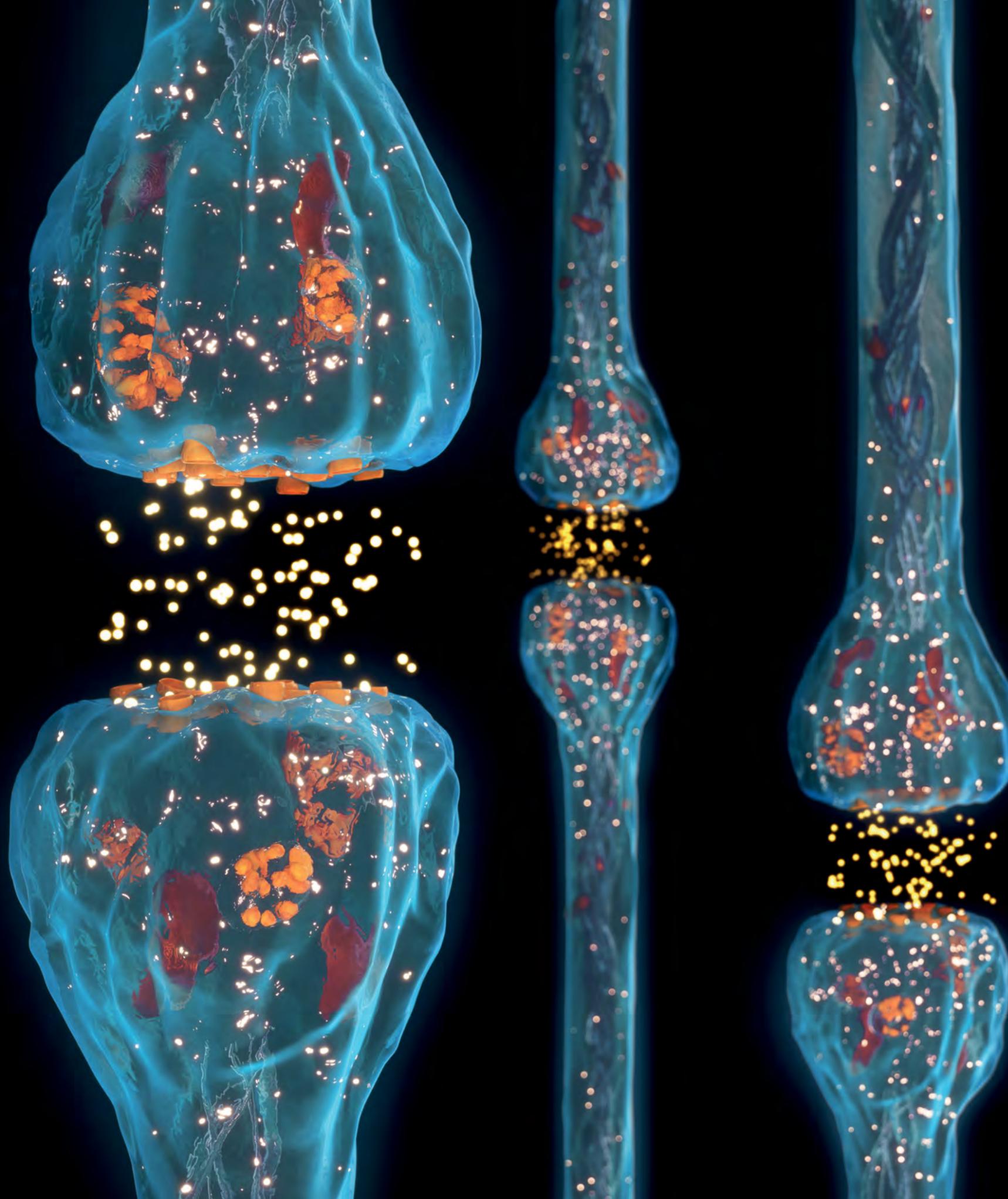
Regulatory challenges

The regulatory challenge is something that can't be stressed too highly. It is difficult for those who don't work in the regulated environment to comprehend just how much time, effort and rigour is required to document that the design, manufacture and use of a system is sufficiently safe for routine commercial use.

It can appear an impenetrable world of endless standards, guidance documents, acronyms and 5 digit numbers – compounded by differences between regulators in different geographies – most commonly the FDA in North America and the Medical Device Directive / Medical Device Regulations in the EU. However, all that's required in the first instance is an understanding of the basic principles of medical device regulation, accompanied by some expert advice from one of many independent regulatory affairs experts. →

“Signal processing is a core aspect of interpreting neurological activity.”

“The mammalian brain is arguably the most complex object in the universe and we still have a lot to learn about it. But our understanding of the brain and the nervous system is increasing at a faster rate than ever before in human history.”



Conclusions

So, it seems that the major breakthroughs in modulating the nervous system and connecting the brain to the digital world won't come about simply through clever app design, 3D printing something or using the latest 3D spectacles. Don't be fooled by these apparent breakthroughs. I'm not denigrating this work – this creativity and application of technology will be important, but such innovations on their own won't be enough. The real winners will be those who are willing to get stuck into the complex, unpredictable realm of neurobiology. They will be willing to draw together experts across a range of disciplines, to look beyond the next clinical study and consider all the issues which a routine clinical therapy or diagnostic tool will face.

In the coming years we will probably start to see deep brain stimulation playing a role in managing Parkinson's Disease. Implanted peripheral nerve stimulation techniques are growing in credibility. It was a sketchy area for some decades but evidence is growing that nerve stimulation (sometimes termed 'electroceuticals') can elicit some measurable and meaningful therapeutic benefits, such as modulation of TNF (Tumor Necrosis Factor) as an alternative to anti-TNF therapy.

The more fantastic treatments such as digital retinas will probably remain in the research domain for a decade. However, limb prostheses which are controlled by brain activity, albeit using external electrodes, will gradually begin to become the norm.

We live in exciting times. The mammalian brain is arguably the most complex object in the universe and we still have a lot to learn about it but our understanding of the brain and the nervous system is increasing at a faster rate than ever before in human history. Ultimately though, it may be cost and regulatory apprehensions rather than understanding which place the greatest restrictions on progress. ENDS

20 years of Team's Human Factors Engineers



Over the last 20 years we have developed reliable methodologies and analytical approaches to meet the requirements of human factors engineering for medical devices.

We analyse the analysable and research the researchable and then we are honest about what is left.

Our Human Factors Group achievements

300+ projects

47+ clients

250+ studies

7000+ participants

1999

And so it begins

- The first HF client project – Inhaler
- Project: measure of trainability of dry powder inhaler



Julian Dixon

2004

HF Analysis

- First formal HF analysis project
- Project: Identification of potential use errors with an insulin pen

2001

Contextual

- The first contextual enquiry in hospitals
- Project: development of a water treatment system for dialysis



Context of use

There are a number of key contextual factors which need to be understood and defined in order to guide your usability activities, challenge your design decision and set the scene for how users will interact with a product. A 'context of use' file outlines these contextual factors and is a very useful foundational document. It should contain:

A description of the intended medical application and human interaction.

- Definitions of the target users, both the primary user population and any secondary user groups.
- Definitions of the target use environments, noting defining characteristics such as the lighting, space, busyness, temperature, etc.
- Identification of the likely use scenarios.

2006

Instructions for use

- First IFU development project
- Project: development of DPI IFU
- IFU development is one of Team's core capabilities

IFU

It is clearly stated by the FDA that the IFU is part of your user interface. It is entirely possible that your IFU is the key part of your interface.

During formative testing, participants may be asked to try and use the device without the IFU. They may later be asked to read the IFU and operate the device whilst following the instructions, and then again without the instructions. This approach can be very interesting as the IFU may actually cause confusion as opposed to preventing it.

Good IFU development is a real skill. Try to embed the IFU creators in the device design and development team if at all possible. It may appear simpler and easier to outsource the IFU design to a third party at the end of development but it's really helpful to write the IFU as you go along. →

2002

Simulation

- First simulated use studies and HF contribution to drug delivery device development projects
- Projects: development of DPI and autoinjector
- We have now observed over 7000 participants in studies



Diane Aston James

2007 International

- First international research
- Project: first disposable subcutaneous autoinjector HF project
- Confirmation of autoinjector IFU changes

2008 Validation

- Project: first validation study – assessment of a vial kit and a reconstituting pen for the treatment of viral condition
- We have since conducted dozens of validation studies

Validation (summative)

The validation study is the final HFE study that is conducted before a device is submitted for approval. This should be a tick-the-box exercise if you've been doing plenty of formative studies as you've been going along.

The FDA will expect you to conduct a study specifically designed to demonstrate that your intended users can use the device safely and effectively.

This is likely to be a realistic simulated use study where environmental factors should be considered such as dim lighting and distractions.

It's really important to remember that the validation study is only one part of the whole HFE summary report. It isn't the only thing which the regulator is concerned with. It's a bit like when you did maths at school and the teacher asked to see your working and not just the answer.

2009



2011



2014 In clinic

- First 'HF in clinic' study
- Project: assessment of inhaler instructions by observation of patients inhaling placebo powder – run under a clinical study protocol



2012 FDA ADCOMM

- Project: supporting our client at an FDA Advisory Committee meeting



Design research

- First design research programme
- Project: early stage work for pharmano, inflammatory disease



“There are many kinds and traditions of research into the relationships between people and things, for example: market research, design research, usability research, clinical research. **Design Research is the label applied to qualitative & quantitative research that is carefully targeted at informing early design decisions, setting direction, inspiring designers and discovering opportunities for innovation.**”

Martin Bontoft, our Head of Design Research

2016 GUI

- Project: first GUI development and test



2015 Smart devices

- First smart drug delivery device HF study
- Project: formative study on an instrumented DPI using Bluetooth prototypes



Placebo

- First non-clinical HF study with placebo
- Project: comparing use of empty devices with devices containing placebo



2017 Robots

- First surgical robotics project
- Project: assessment of a surgical robotic system

Health Care Professional app

- First Health Care Professional (HCP) decision support app
- Project: PC and mobile apps supporting clinical decisions (cardiovascular health)

2019 16 strong!



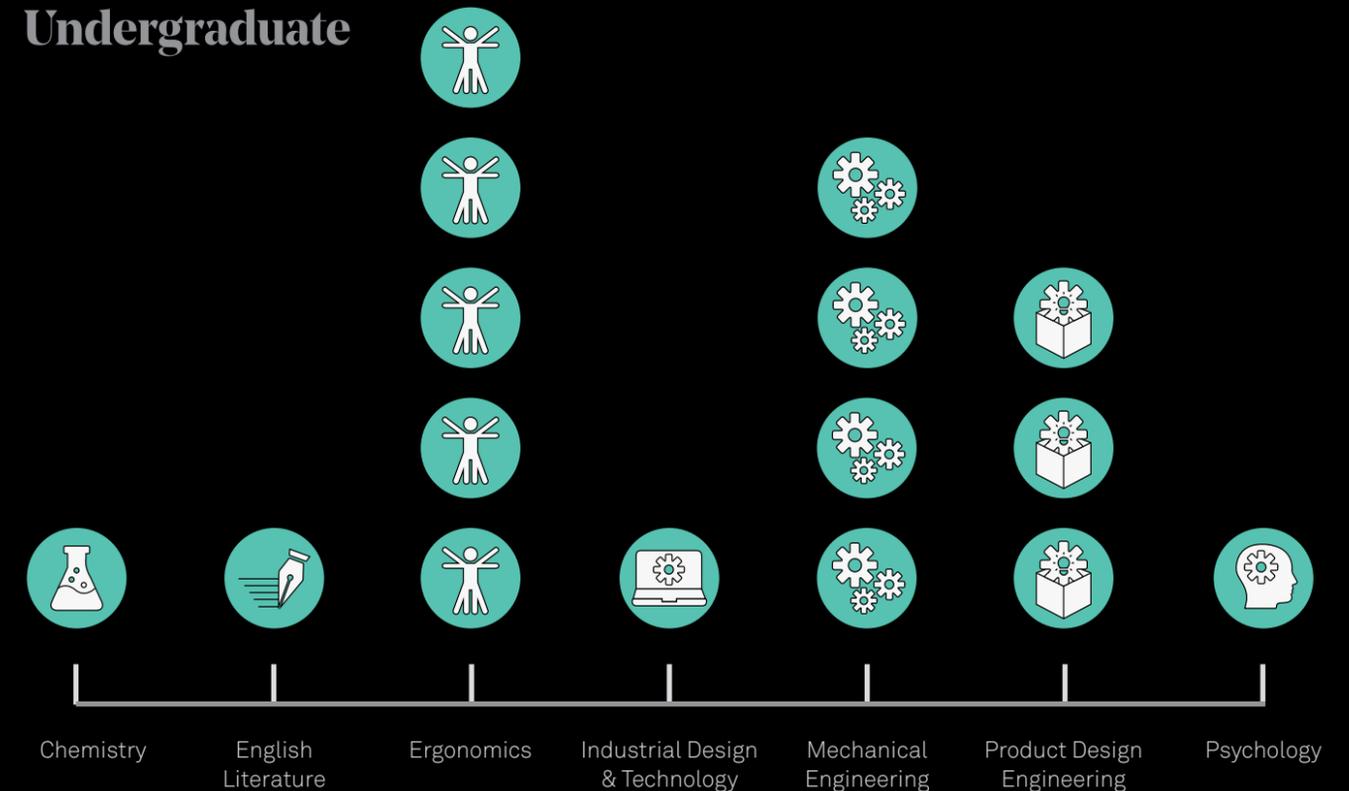
2018 Smart drug delivery device & app

- First commercial smart device & companion app
- Project: HF assessment of smart inhaler and app system

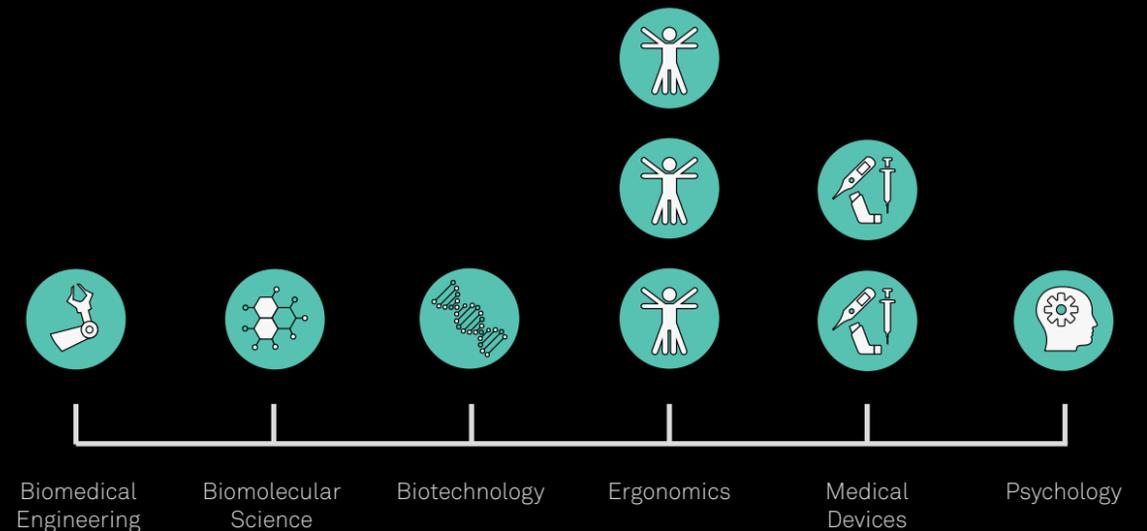


Our qualifications

Undergraduate



Postgraduate



Beyond the inhaler

**What happens to drug particles or droplets
once they enter patient airways?**

How can we understand this better?

**How can we judge what's important for the
patient in device development?**

By Nia Stevens



Drug delivery to a patient's lung for disease treatment involves more than "simply" the performance of the drug delivery device; the mechanics of lung deposition in a patient's lungs on each individual inhalation has a huge impact on the dose delivered. As airborne drug passes from the inhaler to the patient, it leaves a carefully designed and closely process-controlled environment and enters the hugely complex and highly variable space of the patient airways. As device designers and engineers, careful consideration of the patient is key to developing robust and effective products.

Challenges in inhaled drug delivery

Lung deposition is not an exact science, with a co-efficient of variability of 40% being typical ^{(1),(2)}. It is also highly inefficient, as a consequence of the mouth and throat doing a very good job of protecting the lung from airborne matter. Delivery efficiencies are typically around 20-40% of the label dose, with the small number of high efficiency products achieving no more than around 60% ⁽¹⁾.

Low lung delivery efficiency may not be overly problematic depending on the side effect profile of the drug. However a high dose to the throat is associated with dysphonia and oral candidiasis for some steroids, so it may be beneficial to avoid this for those medicines. Variability in dosing is a problem for patients and physicians alike as discussed below.

Nonetheless, the dose benefits of delivering drugs intended to treat local lung diseases via the inhaled route, compared with doses required for oral solid dose delivery, outweigh these disadvantages ⁽³⁾. Likewise, the rapid uptake of drug into the systemic blood plasma can make the lung an attractive choice for some drugs intended for systemic delivery. Understanding lung delivery is an important challenge and ongoing mission for many.

So, what factors affect lung delivery? How can we understand them and even try to manipulate them? →

Easy to control – particle size

Everyone involved in the development of inhaled products will be laughing (if a little ironically) at the notion that controlling particle size is easy, however, in terms of lung delivery, particle size is the most controllable of the various factors.

For delivery to the lung, particles need to be small enough to avoid impaction in the mouth and throat but large enough to impact and sediment once in the lung; typically the target is to maximise the particles in the range 5-1µm⁽²⁾⁽⁴⁾. Nanoparticles smaller than 100nm are also effective at lung delivery⁽⁵⁾ but are more difficult to deliver and handle in manufacturing processes. Particle size also influences the quantity of drug delivered to different lung regions such as the bronchi, bronchioles and alveolated airways, which has the potential to affect efficacy, safety and systemic uptake⁽²⁾⁽⁴⁾. Nonetheless particles of all inhalable sizes deposit in all airways to some extent⁽⁶⁾.

The development and manufacture of inhaled products relies heavily on the measurement and control of particle size. A virtual sub-industry of analytical chemists, instrument manufacturers and data quality systems exists to perform these measurements. However, this only controls one aspect of lung delivery and once particles enter the patient there are a multiplicity of factors to subvert this control.

Challenging to control – inhalation parameters

Inhalation air flow rate, inhaled volume and breath hold duration all affect deposition in the lung.

If patients inhale with higher airflow rates then this results in increased impaction in the throat, and reduced lung dose⁽⁴⁾⁽⁷⁾. The distribution of drug deposition in the lung is likewise affected with impaction in the bronchi increasing, resulting in reduced availability of particles to sediment in the alveoli⁽⁴⁾⁽⁸⁾. However, a rapid air flow rate is often

required to aerosolise the dose of a dry powder inhaler to the requisite fine particle sizes of around 5-1µm. There exists therefore a trade-off in the effects of inhalation flowrate for these devices. The volume inhaled by a patient determines its penetration into the lung and increases the proportion of alveolated airways being dosed⁽⁶⁾. Similarly, asking patients to hold their breath post-inhalation for a few seconds increases the time available for particles to sediment and diffuse and therefore increases the deposited lung dose. Breath hold is particularly important for smaller particles, which have reduced sedimentation efficiency⁽⁹⁾.

Inhalation parameters are manipulable, if not directly controllable. Instructions in patient information leaflets are the simplest and most widespread means of achieving this. However even a well-posed, well-understood set of instructions cannot mitigate the inherent high variability in how each person breathes from day to day⁽¹⁰⁾. Furthermore, many patients do not follow the inhalation instructions correctly⁽¹¹⁾.

Numerous innovations have been developed to help reduce the variability associated with inhalation manoeuvre. Feedback to the patient can be provided via training aids such as flow meters⁽¹²⁾ or an add-on device that produces a tone at the correct flowrate⁽¹³⁾. Smart inhalers are in development that include passive technologies such as flowrate sensors and Bluetooth connection to a mobile phone and some of the most advanced inhalers can dynamically change flow rate resistance during inhalation⁽¹⁴⁾⁽¹⁵⁾.

Nearly impossible to control – patient airways

The size and shape of the patient airways affect how particles are deposited in the lung. In particular, throat

size and shape has been shown to profoundly affect throat impaction and the delivered lung dose⁽¹⁶⁾, with smaller throats trapping more particles leading to reduced lung dose. The size of a patient's lung airways also has some effect on the deposition efficiency, though this is less well characterised⁽¹⁷⁾.

There is very little that can be done to change the size and shape of a patient's airways, beyond the effect that mouthpiece shape may have on the geometry of the oral cavity, for example tongue position, at the time of drug delivery. Posture and the inhalation manoeuvre may also affect

throat shape⁽¹⁸⁾, which changes during the inhalation. However, these do not overcome the basic underlying fact that different people have different sized throats, so this is an unavoidable human variability. Smaller particles display reduced impaction in the throat so the variable effect of throat size on lung deposition may be reduced this way.

Challenging to control – other patient interaction factors

Other factors that may affect the successful dose delivery include how the patient interacts with the device, for example whether they make a good

seal on the mouthpiece with their lips (ensuring air flows through the device and not around it). pMDIs require co-ordination of the dose actuation with inhalation onset, which around half of patients fail to do correctly⁽¹¹⁾. Dose preparation is another challenge. pMDIs require shaking while many DPIs absolutely must not be shaken once opened. For some devices a lever needs to be pushed to a certain point, and others require loading of a capsule. Each of these steps have been shown to be performed incorrectly for around a third to a half of patients⁽¹¹⁾.

Impossible to control – patient disease state

The disease state of an individual patient can affect inhalation parameters and airway size and shape. These differences have been shown to lead to increased lung deposition compared to healthy cohorts, which, though potentially beneficial, may also incur harm and needs to be understood⁽¹⁹⁾. These numerous disease-related factors interact in complex ways.

Patients with lung diseases do not always achieve the same inhalation flowrates as healthy individuals. This is a more significant problem for COPD (Chronic Obstructive Pulmonary Disease) subjects compared to asthmatic cohorts who may on occasion achieve flowrates comparable to healthy individuals⁽¹⁰⁾. COPD patients suffer from hyperinflated lungs and consequently their inhaled volume is significantly reduced as the lung is already partially inflated compared to a healthy individual⁽¹⁰⁾, which results in reduced penetration of the drug particles to the alveolated airways⁽⁶⁾.

COPD affected lungs are subject to airway remodelling. In the bronchi and bronchioles some airways are increased in size by hyperinflation while others feature local narrowing and

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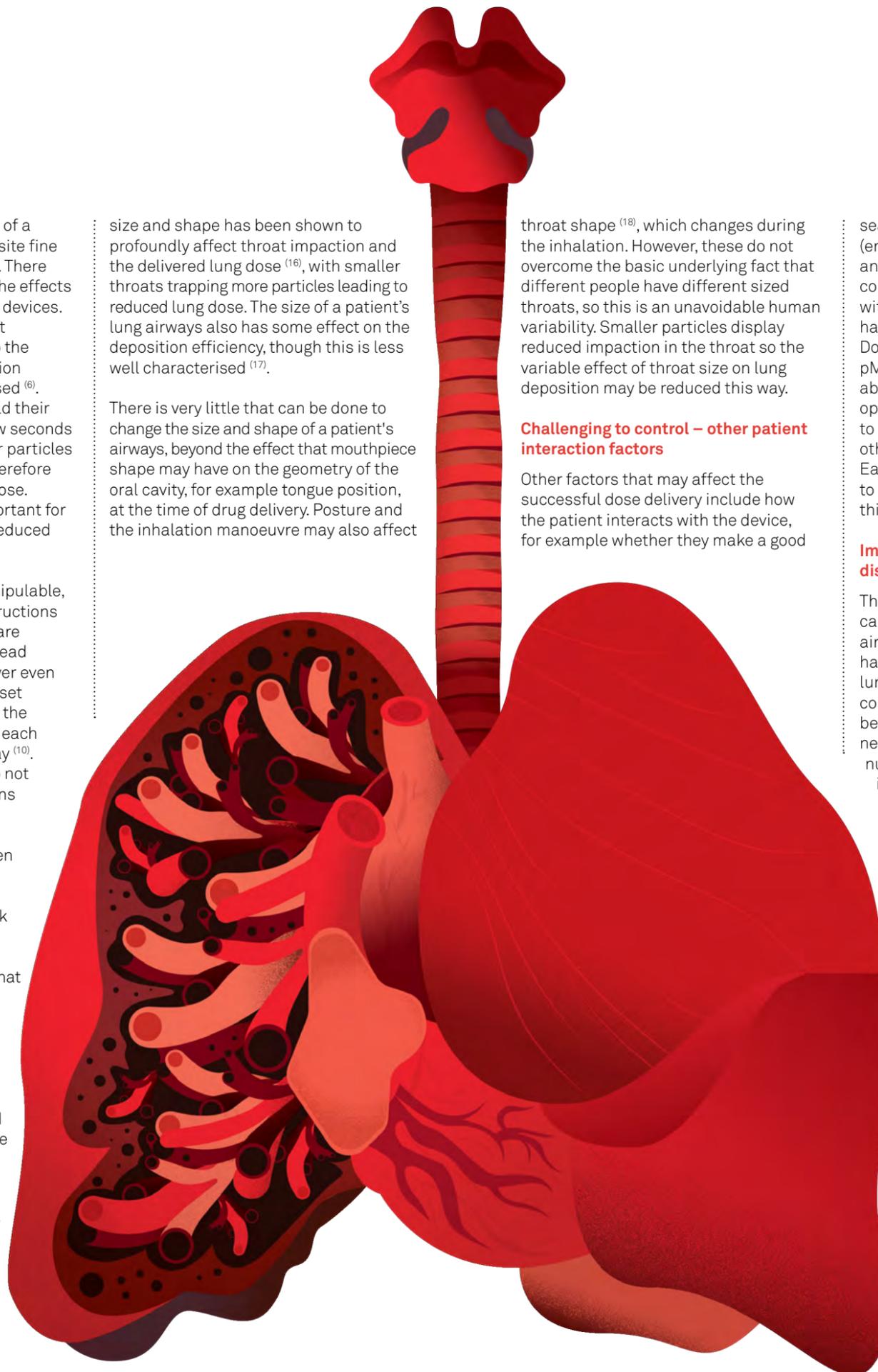
obstructions which reduce the dose passing that point. It may be that these obstructions prevent drug from reaching the part of the lung most in need of treatment, making them reliant on whatever dose passes back into the lung airways from systemic circulation. In the alveolar region, emphysematous voids appear, creating large, irregular spaces that greatly decrease deposition by sedimentation and Brownian diffusion which are heavily dependent on the small size of alveolated airways for efficiency.

Additionally, feeling unwell may make patients distracted, tired and less likely to comply closely with complex inhalation or lip-seal instructions.

Poorly understood let alone controlled – electrostatics

The electrostatic charge of the inhaled aerosol dose is likely to affect the emitted particle size and also has a direct effect on how those particles deposit in the lung.

Electrostatic charge is understood to be a key contributor to inter-particle adhesion forces⁽²⁰⁾ and has the potential to affect de-aggregation and re-aggregation events and hence the particle size emitted from the device and entering the patient. Once in the lung, both mirror charges and field charge effects have the potential to cause particles to be attracted to the airways and for this to significantly affect deposition⁽²¹⁾. Measurement of electrostatic charge is very challenging to do repeatedly and reliably and, compared to other factors, is in its infancy. →



“There exist few easy solutions to achieve the utopian goal of consistent lung delivery. A well-designed device that is simple to use, generates a consistent aerosol that has low sensitivity to flowrate is a good start.”

Nonetheless some recent developments show promise and may help grow our understanding of this much ignored factor in lung delivery. The BOLAR instrument measures the bi-polar charge for different particle sizes emitted from an inhaler and has greatly furthered understanding of charge effects. BOLAR data shows the aerosol plume to contain large quantities of both positive and negative charge that greatly exceed the net charge⁽²²⁾. Electrostatic charge effects have been incorporated both in lung deposition modelling⁽²¹⁾ and DEM powder flow modelling tools⁽²³⁾ that have the potential to model de-aggregation events, which BOLAR data may be fed into.

Patients need easy-to-use devices that are consistent

So, what do patients need most from their inhaled drug product?

Patients try out different doses and different drugs, together with their physician, to understand what medicine best controls their disease symptoms. In order to get meaningful and accurate feedback on drug performance, patients need consistent drug delivery each time they use the product. Physicians likewise need consistency between patients so they can learn from experience.

It should be noted that common dosing scenarios where dose delivery variability has little impact on patient outcomes do exist. Once the overall drug dose has reached a certain level then the available pharmacological receptors become saturated and additional increases in drug dose have no additional efficacy. In this instance, the patient treatment is robust to lung delivery variability. However, if a patient is evaluating which dose works best for them, for example

by switching to a higher dose product, then they are likely to be at a low enough dose that changes to that dose result in efficacy changes i.e. the drug receptors are not saturated. Unintended and uncontrolled changes in lung delivery efficiency due to its inherent variability therefore may likewise affect efficacy.

Equally important is device ease of use. There is overwhelming data showing that a large proportion of patients make errors when using their device⁽¹¹⁾, moreover incorrect inhaler usage has been shown to be linked to poor health⁽²⁴⁾.

High tech solutions are not necessarily the best. While a phone app or sensor-enabled inhaler that measures flowrate is one way of obtaining dosing consistency, a product with reduced sensitivity to flowrate may achieve the same outcome with less complexity for the patient and regardless of their engagement with their therapy.

There exist few easy solutions to achieve the utopian goal of consistent lung delivery. A well-designed device that is simple to use, generates a consistent aerosol that has low sensitivity to flowrate is a good start. A breath-actuated mechanism can improve outcomes for pMDIs by taking co-ordination out of the patient's hands. Additionally, there will undoubtedly be many patients who benefit from the high-tech solutions. The task of getting drug into the lung is one that will most likely continue to challenge scientists and engineers for decades to come! **ENDS**

Lung deposition mechanics

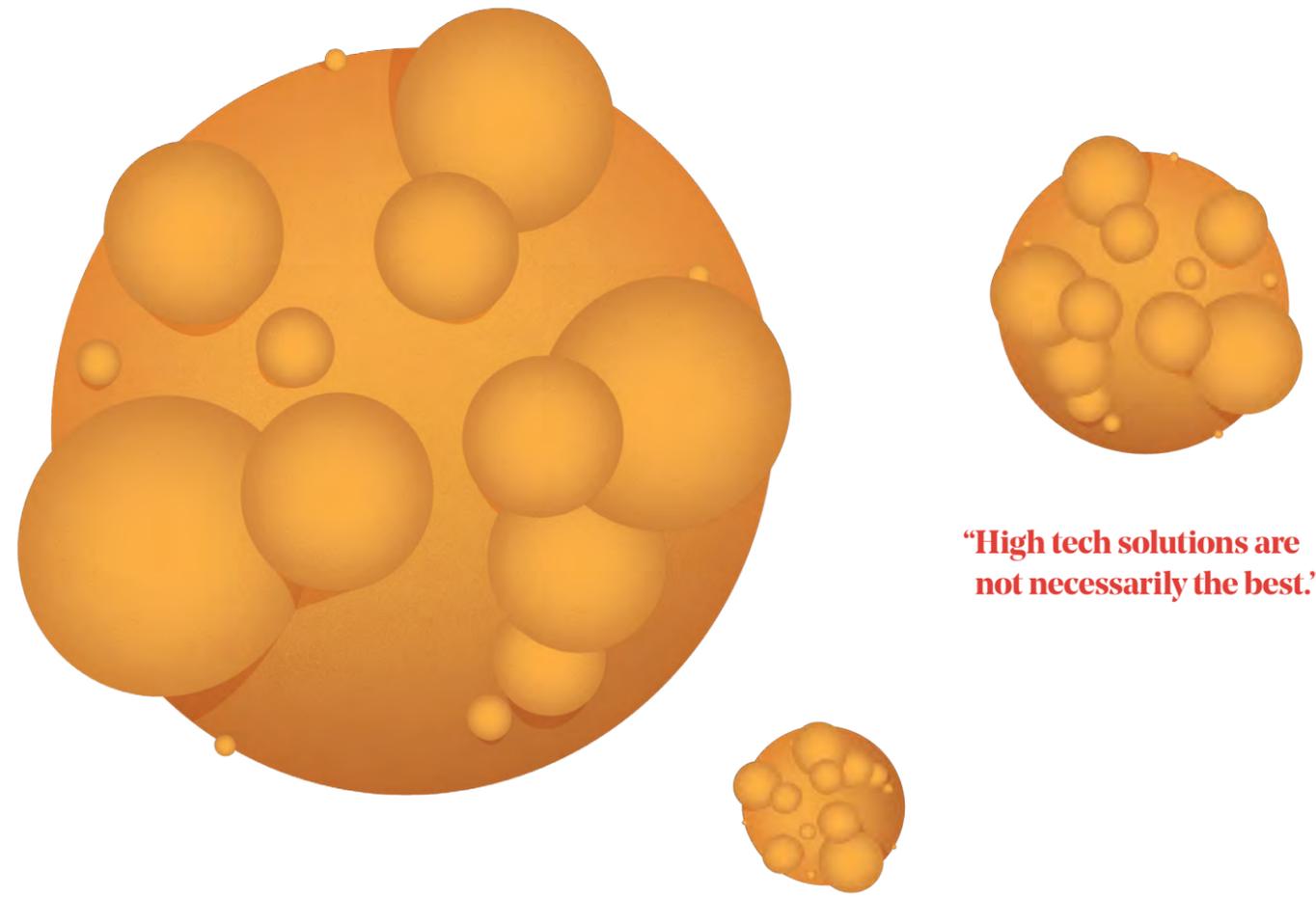
The fate of particles in the lung is determined by four different deposition mechanisms: aerodynamic impaction, sedimentation, Brownian diffusion and electrostatic attraction (interception of long fibrous particles is the fifth mechanism but is typically not relevant to inhaled drug products).

Aerodynamic impaction describes the ability of a particle to follow the airstream. The larger the particle the more likely it is to “crash out” of the airstream and deposit on an airway. Likewise, particles travelling more quickly will impact more readily.

Sedimentation efficiency describes simply how particles settle and deposit in the airways. They do so at their aerodynamic terminal velocity so like impaction this is an aerodynamic event. Larger particles are less influenced by aerodynamic drag and sediment to a greater degree in the time available.

Brownian diffusion describes the random trajectory of particles small enough to be influenced by the net effect of collisions from air molecules. This mode of deposition increases as particle size decreases and is a significant deposition mode for nanoparticles.

Aerodynamic particle size, a driving parameter for both sedimentation and impaction, is typically measured using instruments such as Cascade Impactors⁽²⁵⁾. By this means, particle density and shape effects on particle flight are also accounted for.



“High tech solutions are not necessarily the best.”

Footnotes

* Nia is a mechanical engineer involved in the development of drug delivery devices. Prior to joining Team she spent more than a decade at GSK in their Inhaled Delivery Science and Device Development groups.

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10 issues in the development of surgical devices

(that don't get talked about much)

By Iain Ansell



The media coverage of surgical devices is often dominated by robotics, to the extent that the public could be forgiven for assuming the majority of procedures were carried out robotically – actual figures for robotic surgery as a percentage of all surgery are hard to come by but <10% of US procedures seems reasonable.

Similarly, negative press associated with surgical implants has even got as far as Netflix. However, talking with clients long established in surgical device development there are several issues that are potentially limiting innovation. These underlying issues get very little publicity but have a great impact on the industry and its ability to develop and successfully market new devices to bring patient benefit. Following is a brief commentary on some of these issues.

01

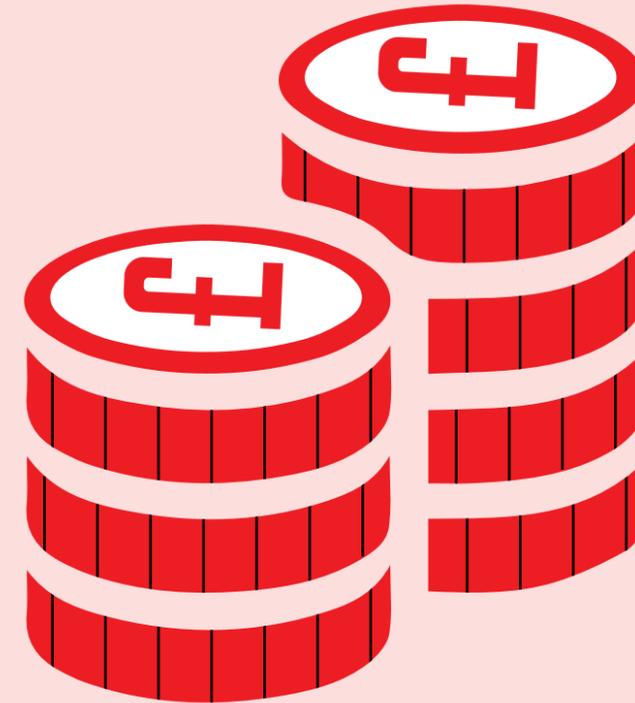
Access to theatres for observation

In order to uncover unmet needs in surgical procedures (no device exists, or existing devices are deficient) direct observation of live procedures is considered the gold standard. Access to theatres is becoming more difficult, as facilities tighten up access due to increased focus on H&S (patient and staff), patient confidentiality, etc. There does not appear to be a single reason for this increasing culture of conservatism related to theatre access for R&D staff; could it be an indirect consequence of legislation such as the Sunshine Act (undue influence of physicians), HIPPA or GDPR (both data protection/privacy)?

Device developers are having to work through increasingly bureaucratic processes to place technical staff in theatres. Commonly several workarounds are used to gain insight including increased emphasis on interviews, observing simulated surgery, video analysis and observation suites in teaching hospitals.

**OPERATION
THEATRE**

PLEASE DO NOT ENTER



02

Increased cost focus

Traditionally surgical devices that offered increased performance or functionality received a warm welcome in the market, particularly from surgeons eager to adopt the latest technology. Increasingly payers are challenging the need to purchase improved devices at higher cost, needing to see evidence of clinical benefit aligned to a cost benefit or overall cost effectiveness compared to existing treatments. In the UK NICE (National Institute for Health and Clinical Excellence) has a formal system for evaluating cost effectiveness of new treatments, and is a good reference for healthcare economics.

This professional scepticism from payers makes placing and successfully marketing a new product more difficult. Slower uptake will result in a slower return on investment for the device company and mean clinical evidence will take longer to generate. A device selling at low initial volumes with a slower increase in market penetration will limit or slow the benefit of scale, where increasing manufacturing volumes, and associated efficiency reduce device cost over time.

“Access to theatres is becoming more difficult, as facilities tighten up access due to increased focus on H&S (patient and staff) and patient confidentiality”

03

Needs-led vs tech push innovation

Device companies are constantly scouting for new technology to incorporate into next generation devices. The technology is identified, assessed and developed to give an advantage (e.g. size, speed, ease of use) over current devices. Sometimes this technical advantage is divorced from procedural need.

Increasingly the market will judge the potential of an improved device in context of the overall procedure, or the complete treatment. So as an example, a powered device that allows faster transections might not be judged to offer any meaningful overall benefit when the actual cutting time is a small percentage of the procedure and certainly not considered to be the limiting step.

Innovating in areas identified as bottlenecks or meeting previously unmet needs is far more likely to yield devices that can demonstrate both clinical and overall cost benefit. This requires a more in-depth view of the context in which devices are used, observation of procedures (or even the end to end life of an instrument) to identify issues with current devices and unmet needs and dialogue with surgeons and other stakeholders on an ongoing basis. →

04

Democratisation of procedures

Traditionally device companies have collaborated with leading surgeons, or Key Opinion Leaders (KOLs) to develop novel devices that allow new beneficial procedures to be carried out more effectively, this can have the effect of allowing a greater patient population to benefit. Once a device is prototyped, or fully launched KOLs can drive adoption by publishing results of studies, etc.

Another approach to accessing a greater population of patients is to enable fewer expert/specialist surgeons to carry out procedures, or to take procedures from the theatre to the doctor's office. This could involve developing devices that give greater confidence, or enable a less difficult technique to achieve the same aim. There is much talk that surgical robots will democratise surgery, but perhaps a greater opportunity is with more humble devices, or surgical education programs?

Accessing these surgeons and uncovering the features that a new device would need can be very challenging. Device companies have an existing user base, which they can access through representatives, however accessing people who do not use your devices or carry out certain procedures is more challenging. Additionally, entering into a dialogue can be difficult, knowledge of the procedure will be limited and there is a risk of the device company feeling they are belittling the doctor.



“There is much talk that surgical robots will democratise surgery, but perhaps a greater opportunity is with more humble devices, or surgical education programs?”

05

Incumbents' advantage over the newcomer

There has been significant consolidation in the surgical devices landscape with mergers and acquisitions creating very large organisations offering numerous devices across a range of procedures. This offers advantages in terms of scale, allowing large R&D budgets, and the ability to discount to payers based on volume of business – and what buyer would not want to drive down procurement costs? However, a smaller new entrant with a novel device will find it hard to displace a major, when large procurement contracts are in place.

Similarly established medical device companies have strong representative-to-surgeon relationships, offering advice, training, and so on. A new entrant will struggle to establish such a relationship, and could therefore fail to gain vital feedback on devices in development, or struggle to achieve adoption after market introduction.

06

Divergence between academic surgeons, med device companies and the bulk of surgical procedures

Med device companies need to concentrate on volume of procedures both to sell an increasing volume of devices and to gain the clinical evidence to convince others to adopt their device, however their strongest surgeon relationships are often with leading surgeons pushing the boundaries of surgery. Academic surgeons rightly concentrate on the education of the next generation of surgeons whilst driving the overall discipline of surgery.

Meanwhile the majority of procedures, particularly in the US, are carried out in smaller, less specialised centres by surgeons carrying out a greater range of procedures at lower volume than their specialist colleagues. The focus of the medical device companies, and particularly the feedback gained during innovation and development is diverging from some of the groups who should be participating. →

“However, a smaller new entrant with a novel device will find it hard to displace a major, when large procurement contracts are in place.”

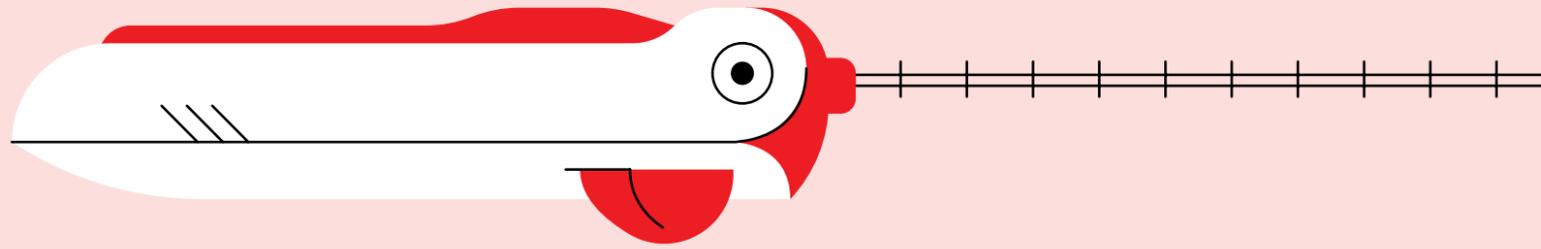
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Regulatory pathway

The vast majority of medical devices are approved in the US via the 510k or exemption route. This is entirely sensible given many are based on, or very similar to existing devices, or made from the same materials. The FDA exists to regulate devices and drugs, not to regulate the practice of medicine, or in this case surgical procedures. The incremental regulatory burden of a PMA is a major disincentive to the developer – and this might limit the development of truly novel devices.

An analogy to the advantage of the fast follower in consumer devices can be drawn, with the follower benefitting from the first market entrant's significant investment in market development. The innovative medical device will have to establish the regulatory pathway without a clear predicate, and then develop the market: following medical devices will benefit from both these efforts.

“A start-up with a novel device will not be in a strong position to adopt the same tactics.”



08

Reimbursement basis

Diagnosis Grouping (US) or NHS tariff (UK) are costing systems that seek to standardise the cost of providing a treatment and paying the provider this standard amount rather than traditional 'cost-based reimbursement' or to use more general industry parlance 'cost plus'. This often influences the amount (or perhaps perceived amount) that a medical device can cost the user. It can be argued that fixed cost per procedure should drive innovation, devices that offer a reduction in overall treatment cost, or are simply cheaper should be 'easy' to sell to healthcare providers, as they allow improved margins on providing the procedure – the practice is often more complicated.

At conception, or during the development process comments like 'I get this will reduce pain, or make a procedure easier – but how am I going to evidence this?' often crop up, suggesting that worthy devices might be dropped because they disrupt the status quo....

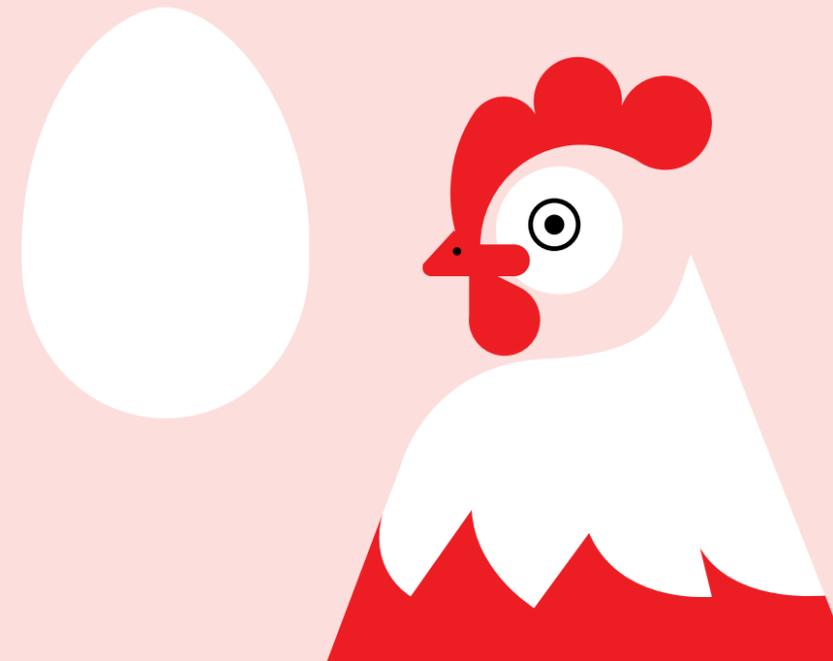
09

Producing clinical evidence

After approval a device can be marketed and used, but volume adoption increasingly depends on producing evidence of clinical efficacy and overall benefit of adoption. This can only be generated by a large volume of procedures being carried out with the new device, but if the new device costs more why would providers procure it? A classic chicken and egg scenario...

Major device companies will employ various strategies to overcome this situation, providing samples to key surgeons, discounting or sponsoring research. A start-up with a novel device will not be in a strong position to adopt the same tactics.

“I get this will reduce pain, or make a procedure easier – but how am I going to evidence this?”



10

Training and habit

Surgeons require many years of training and practice to become fully proficient at procedures. Many surgeons stick to tried and tested techniques and devices, for good reason – they are trained and therefore the outcomes are more predictable (low risk). Device companies invest in surgical training centres and thus upcoming surgeons become familiar with these devices and have a natural preference to use these on an ongoing basis. New devices and techniques will potentially have a steep learning curve and hence are difficult to justify incorporating into everyday practice.

In a recent report on the uptake of minimally invasive surgery (MIS) in the UK's National Health Service (NHS), one of the limiting factors reported was training and access to training for current practitioners of open surgery techniques. Interestingly another barrier to adoption was the forthcoming robotic era, why train in the difficult field of MIS when robots will make adoption easier!

So what?

The above commentary seeks to highlight potential barriers for innovations but does not necessarily offer solutions. The issues are complex, intertwined and ingrained and as such solutions will take significant effort in identification, lobbying, and revised practice. In future articles we will expand on several of these issues offering a more detailed commentary, and suggesting how the future might look. ENDS



“A team is a group of individuals working together to achieve their goal.”

How can we build the perfect team?

Before approaching this question, we must first define what exactly makes a team. Innumerable possible definitions all seem to share three common elements: group, purpose, and interdependence. A team, therefore, is a group of individuals working together to achieve their common goal.

Forming a team is simple – we select and bring people together often based on technical competence. However, curating a productive, high-functioning and effective team is less so. How can we, collectively and as individuals, promote the success of a team? ‘Teamwork’, though crucial when effective, is too expansive a topic; instead we’ll examine key areas that can tangibly impact a team’s success – the lifecycle of a team, culture and group norms, and the role of self-awareness.

By Andrea Pybus



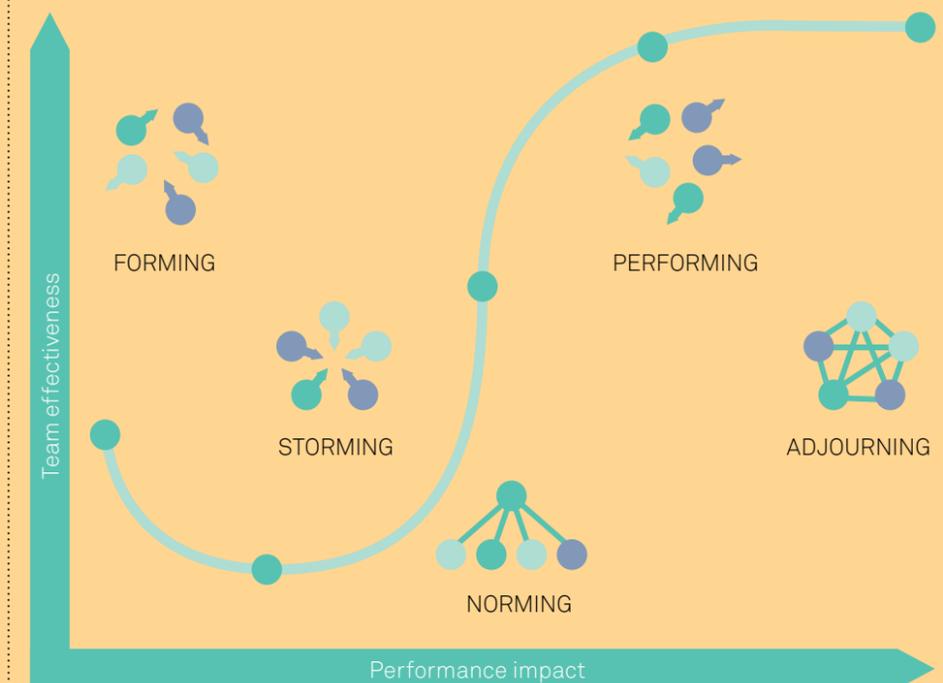
What is the lifecycle of a team?

It can take some time for a team to develop, a process which formed the focus of Bruce Tuckman’s research which started in the 1960s. Tuckman’s article ‘Developmental Sequence in Small Groups’ 1965, expanded following further research in 1977, concluded that teams typically go through 5 key stages as they form and develop: forming, storming, norming, performing and adjourning. His team development model (pictured) identifies the interactions that occur within teams at each stage, as well as the types of feelings and behaviours associated with each.

For example, Tuckman identified that, when first brought together, there is generally a period of getting acquainted with fellow members within a team. People are often hesitant to initiate activities and take on responsibility at this stage, looking instead to the team leader for direction.

The fourth stage, performing, is that which we aspire to or strive for, in seeking to achieve the ‘perfect’ team. It’s at this stage that we see team members taking greater responsibility for tasks and relationships, thus achieving effective and satisfying results. Each team member uses their initiative to assess external forces and progress easily through milestones, thus requiring less leadership. However, many teams never reach this stage, and may move backwards and forwards through the various stages over time.

Tuckman's Group Development Model



FORMING:
Sounding anxious and hesitant, feeling out other team members, getting acquainted, learning roles and responsibilities, understanding team goals, looking to team leader for direction.

STORMING:
Effectiveness reduces, disagreements about role and goals, struggling to establish place in group, forming cliques. Team leader required to facilitate conversations and judging level of communication can be tricky.

NORMING:
Beginning to work more effectively, respecting each other’s opinions and differences, agreeing on team rules, trusting and helping each other, making progress on the project, not relying on team leader as much.

PERFORMING:
The team is performing at a high level, making decisions and solving problems quickly and effectively, working independently. Light touch management.

ADJOURNING:
Team members have bonded and are now likely to move in different directions as the project comes to an end. Feelings may be of sadness and uncertainty about what next. Focused, purposeful and conclusive. Celebration for team’s successes and lessons learned. →

Project Aristotle – why do some teams succeed where others don't?

Tuckman's model acknowledges that some teams progress to succeed, while others struggle. In 2012, Google kicked off Project Aristotle⁽¹⁾, which saw statisticians, organisational psychologists, sociologists and researchers analyse hundreds of teams over three years trying to find the recipe for building the perfect team.

The research and analysis remit of the project was massive. They looked at social interaction, gender, hobbies, education, personality, team boundaries, performance, reward structures and more, all with the aim of establishing the key identifying features of a successful team.

The conclusion, however, after three years of extensive research, was that the composition of a team made no difference to its effectiveness; there were no strong patterns in the results and team effectiveness seemed to be a lottery.

It wasn't until a researcher happened across research into 'group norms' – behavioural standards and unwritten rules that govern how we function when we gather – that the data was revisited and the significance of such 'unwritten rules' or 'team culture' was discovered. This research found that though norms can vary hugely, their influence is profound, a revelation which led to the project's final conclusion. After looking at hundreds of interactions across hundreds of teams, they concluded that influencing team norms was key to improving performance. But which norms?

Research on Group IQ, published in Science in 2010, had pointed to the importance of group norms, identifying two behaviours that collectively intelligent teams generally displayed:

- 1) Equality in distribution of conversational turn taking (members speak roughly the same proportion of time)
- 2) Above average social sensitivity (intuiting how others feel based on tone of voice, expressions and other non-verbal cues)

These two traits are broadly recognised as contributory to a feeling of psychological safety and, in reviewing the data, were also found present in the higher-performing teams examined during Project Aristotle. Rather than the lottery initially suggested by the results, there was a strong correlation between perceived psychological safety within a team and high team performance. Google concluded that clear goals and objectives alongside a culture of dependability were important factors, but that, above all else, psychological safety was critical to make a team work.

The results aren't revolutionary; in the best teams, members listen to one another and show sensitivity to feelings and needs. These behaviours create psychological safety, allowing people to feel as though they can contribute and show empathy, which helps develop better relationships within a team.

Both the Google research and Tuckman model focus on these relationships between individuals; finding strategies to increase human connections can promote perceived psychological safety and thus move a team through the development cycle towards high performance.

So, what can we do at an individual level to influence team performance?



“In the best teams, members listen to one another and show sensitivity to feelings and needs of others.”



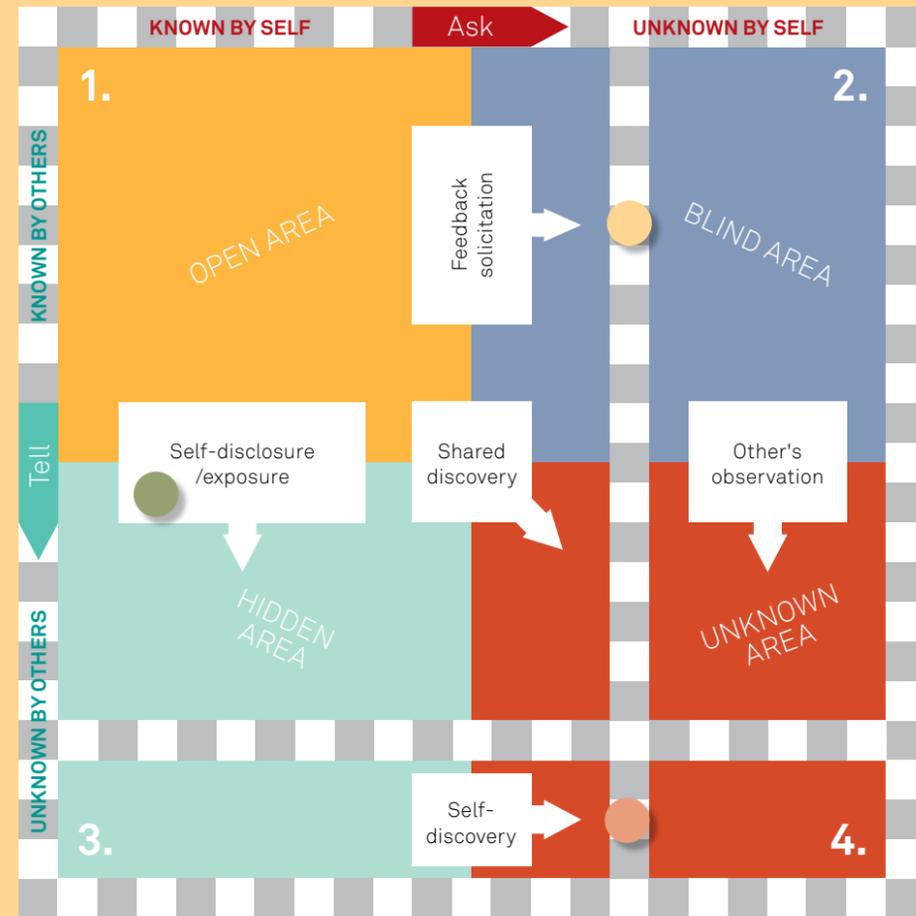
The significance of self-awareness in team performance

Consciousness of our own characteristics and feelings, and ability to increase our self-awareness, though seemingly intangible, help us to collaborate more effectively in team settings. Such self-awareness prompts us to consider the character and feelings of others, thus potentially pre-empt frustrations or conflict arising (or at least help us to consider effective approaches to resolving these quickly).

Developed by Joseph Luft and Harry Ingham in 1955, the Johari Window is a model that can help to visualise a self

discovery process, it is split into four quadrants: the open area, blind area, hidden area and unknown area; through communication and cooperation, the balance between the four areas can change.

- The open area denotes everything you know about yourself and are willing to share with others. We increase our open area by asking for feedback and disclosing information to others, so the more we share, the more open the connections we can have. This is where the main value of the open area lies; it aids the development of interpersonal relationships by building rapport and trust in relationships.



- The blind area encompasses characteristics that we do not know about ourselves, but that others within the team are aware of. With the help of feedback from others, we can become aware of some of our positive and negative traits as perceived by others, and overcome some of the personal issues that may be inhibiting us or the dynamic of the team. When feedback is given honestly it reduces the size of our blind area – for example, interrupting people before they have finished making their point, which can cause frustration. Sometimes we don't realise these aspects of our character until they are pointed out.

- The third quadrant, the hidden area, contains aspects of ourselves we may be aware of, but don't want others to know. This could include vulnerabilities, such as an aversion to public speaking.

- The final, unknown, area is unknown to both ourselves and anyone else. By working with others, it is possible for us to discover aspects of our character that we may never have appreciated before, qualities such as:

- an ability that is under-estimated or untried
- a natural ability or aptitude that we don't realise we possess
- a fear or aversion that we don't know we have
- conditioned behaviour or attitudes

Soliciting feedback and disclosing information to others is eased, and more likely to be reciprocated, if it is a part of 'group norms'. Returning to the findings of Tuckman and Google, a psychologically safe team environment makes this process of disclosure easier, and should aid our journey to high team performance. →

Personality and the role it plays in team performance and development

Reflection on our own character can enhance self-awareness and help us better understand and relate to other members of a team. Generally defined as ‘what makes you “you”’, personality encompasses all the traits, characteristics and quirks that set us apart from everyone else.

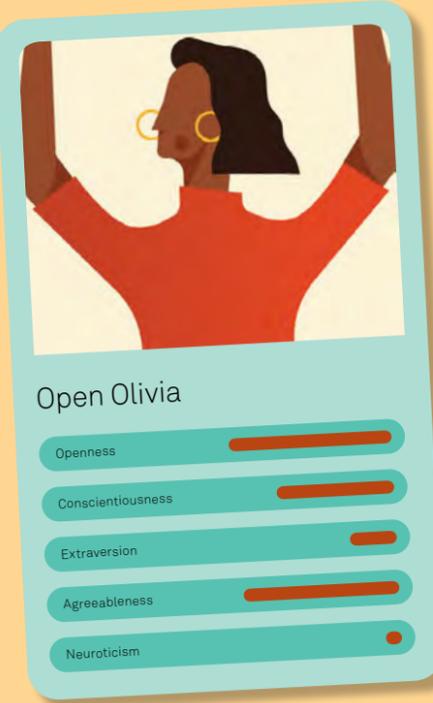
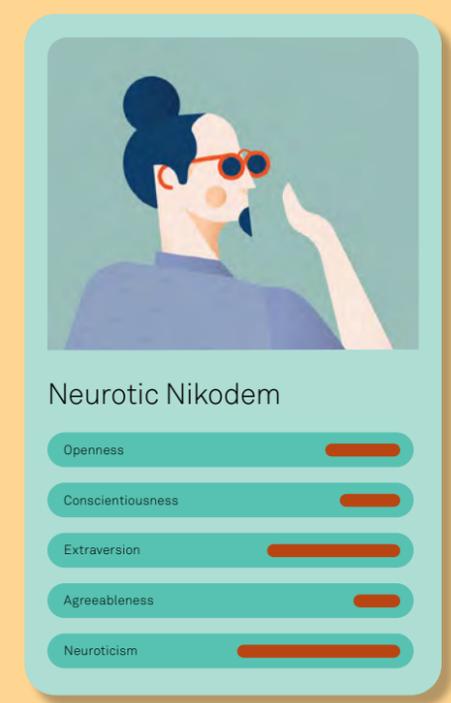
Research suggests that diversity of personality can make teams more effective, with more varied ideas and perspectives, stimulating innovation and aiding problem solving. It’s clear that personality is therefore an important consideration in the pursuit of the perfect team.

How do we measure personality?

Centuries of research, dating back to Hippocrates, have looked for reliable ways to conceptualize, assess and measure personality.

From all this research, the most prevalent personality framework is the “Big Five,” or the five-factor model, which describes 5 dimensions of personality or traits: openness, conscientiousness, extraversion, agreeableness and neuroticism (often recalled by the acronyms OCEAN or CANOE).

Experts have developed psychometric and personality profiling tools, such as the Facet 5 used at Team, support the exploration of how similar or different our personality traits are from those of others. This aids our understanding of our own personality – how we like to approach our work and working with others.



There are many tools, however the typical exploration process starts with a self-assessment questionnaire containing carefully prepared questions which explore attitudes, opinions and preferences that cover the OCEAN factors. Each of the five personality traits represents a range between two extremes and the tool attempts to measure the amount of each factor present in our personality.

Our responses to questions relating to each trait are then combined and converted to produce a score on a scale of 1-10. This score is then compared to a Norm Group (of others who have responded to the questionnaire). The score is then plotted on a range or scale. It is the degree of deviation from the norm that starts to gauge how our ‘measure’

of a trait compares with that of others and what that means for interaction and working in teams.

The diagram below presents each trait as a scale with descriptions associated with the extremes relative to the ‘norm’. Applying an individual’s scores to the OCEAN traits then allows us to generate a profile of likely behaviours.

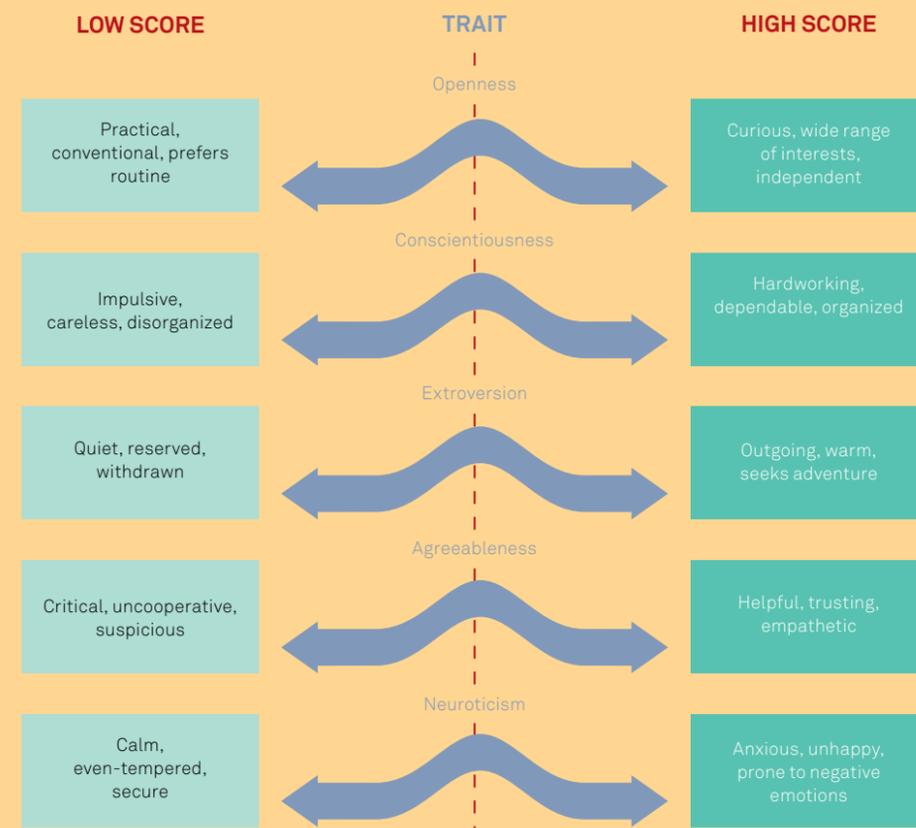
Insight through comparisons

When it comes to the results of such assessments, it is important to stress that there are no good or bad outcomes; all high and low scores present both risks and opportunities in a team setting. For example, a low score on Extroversion may manifest as a more reserved, private personality, perhaps less obvious display

of enthusiasm. The risks associated with this score could be appearing distant from colleagues or difficult to engage, and may be interpreted as a lack of interest or involvement. Conversely, the potential associated strengths could be a willingness to listen as much as talk, understanding before offering opinion, and a tendency to not to talk over others or override their decisions.

The insights from such tools are a great input to the process of increasing self-awareness and allow us to consider what strengths our personality can contribute to a team and what aspects of our personality could present challenges for us or for those working with us. This insight offers greater opportunity to consider how we develop and adapt our behaviour when working in different team environments, with the many unique personalities we will come across, and how the team leader can assemble and organise a team to play to strengths.

Recognition that creating this environment is not solely the responsibility of the team leader and that investing in self-reflection, seeking constructive feedback and thoughtfulness about our impact on others will all contribute to reaching the aspirational ‘Performing’ stage in a team’s development and the achievement of the team’s goals. If we feel we can share some of this insight with our team leader or other team members, increasing the open area as the Johari model referred to it, this may help to accelerate the development of psychological safety, encouraging others to be equally open. We know that when working in a team where we feel safe expressing our opinions, believe there is equality of opportunity to contribute and we are sensitive and supportive to one another’s needs, we are more likely to perform at our best. And let’s face it, it will be more fun for all! ^{ENDS}



Most people score somewhere in the middle of these two extremes

Footnotes

1. New York Times, Feb 25, 2016 "What Google learned from its quest to build the perfect team."



Cybersecurity

A beginner's guide to secure medical device design

By Mark Emery



A connected medical device is any portable medical device with some form of data connection to a partnered smart device or networked application. These devices are wirelessly connected to a cloud application that performs administration, data collection, or big data analysis.

Connected devices can be passive data gatherers (e.g. blood pressure monitor, glucometer) or active (e.g. a wireless pacemaker). If such devices are not secured, then private data can suffer un-authorised access (passive device), or worst case, a patient's physical health can be threatened by un-authorised agents (active device).

This article peels back the lid of a typical connected device and walks through the software and system design of its construction. Points of vulnerability to data attack are identified, with advice given how to design a secure system.

What is cybersecurity? And why is it now a 'thing'?

There is no single consensual definition of cybersecurity. The best guidance is perhaps that delivered by Wikipedia, "Cybersecurity, ... is the protection of computer systems from the theft and damage to their hardware, software or information, as well as from disruption or misdirection of the services they provide".

Smart wireless 'connected' devices are becoming ubiquitous, against a backdrop of growth in 5G and IoT. The threat to the security of device data is accelerating and hard to ignore. The risk of attack is further compounded by a general lack of threat awareness (manufacturers and consumers) and mature regulation.

Meanwhile, increasing complexity, cost, and time to market pressure is driving a manufacturer supplier market for common hardware platforms and highly integrated chipsets. Increasingly, connected devices are being designed around these homogenised platforms. This has resulted in the endemic reuse of common hardware platforms, software, and the toolsets used to build them.

Whilst open platforms and easily accessible software provides a lifeline to productivity in a fast-moving market, it comes with risk. The consequence is a proliferation of common vulnerabilities, know-how, and easy access for hackers to inspect and modify the running of devices, and to gain access to device operations or sensitive data.

Worse still, the rise in wireless connectivity massively increases the vulnerability of devices. Hacking used to be an activity requiring physical proximity, but it can now be done remotely, at a far reduced risk, on a scale of one-to-many.

What are the threats?

The worst-case scenario of a cybersecurity breach is physical harm to the end user or patient.

Aside from patient wellbeing, a breach can have dire commercial consequences for a manufacturer, and consequences of trust and reputation for stakeholders such as doctors, medical bodies, or institutions. Increasingly, as regulations are introduced and mature, and end customer awareness improves, manufacturers or organisations without rigorous cybersecurity measures could find themselves excluded from key regions and markets.

Threat	Impact on manufacturer	Impact on user
Loss, interference or disruption of data	<ul style="list-style-type: none"> - Financial loss - Trust and reputational loss - IP theft 	<ul style="list-style-type: none"> - Privacy loss - Personal distress - Loss of diagnosis or treatment, causing indirect physical harm
Denial of service	<ul style="list-style-type: none"> - Reputational loss 	<ul style="list-style-type: none"> - Denial of treatment

“ The rise in wireless connectivity massively increases the vulnerability of devices. Hacking used to be an activity requiring physical proximity, but it can now be done remotely, at a far reduced risk, on a scale of one-to-many.”

Scope

For a typical simple connected data device, the user interacts via a screen and buttons (MMI) or via a remote 'connected' wireless application (a web page). These are the interaction points where a user would exchange or manage data with the device.

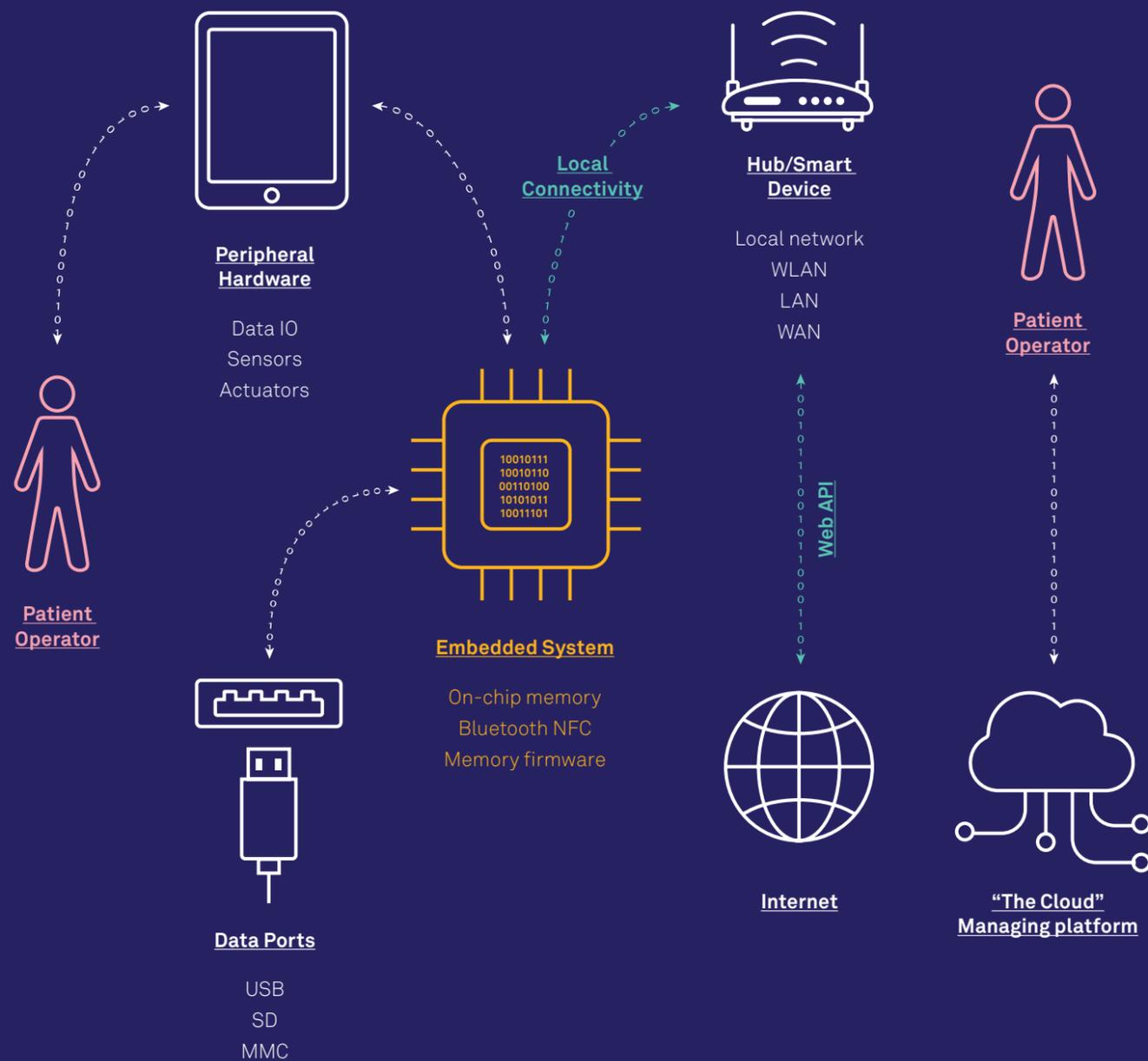
If we were to peel off the lid, and look inside the device, the illustration overleaf shows a typical embedded architecture that might be found. Aside from any specific medical sensors or controls, the electronics building blocks would be similar for any typical medical or IoT consumer device.

At the heart of the device is a highly integrated microprocessor device, on a single chip. This chip runs the application software and interfaces to the MMI and sensor-control components. It also provides connectivity to the internet (cloud) or a paired wireless device.

Vulnerabilities

At any point that data is entered, stored, manipulated, or moved it is vulnerable to cybersecurity attack. How may we mitigate the risks against these attack points? →

Architecture of a typical connected medical device



User login



Vulnerabilities

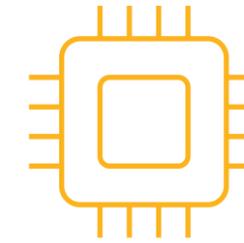
The biggest source of vulnerability is at the point of user entry, the login access points. The simplest breach is to obtain or guess a user's login credentials. With a bit more knowledge and persistence, a hacker can potentially 'brute force' guess a secret password; modern computing power can easily iterate through millions of 'guesses' in a short time period.

Mitigations

There are established good practices for managing passwords and their authentication, covering process and encryption technologies:

- No default passwords.
- Password strength: the better the strength the higher resilience to brute force attack.
- Passwords are not stored on the device as clear text but stored as irreversible Cryptographic Hash codes (e.g. SHA-256). This will prevent a hacker from 'peeling open' a device and discovering user access details.
- Limit the number of password entry retries and force time lock-outs between attempts.
- Expiration and (remote) revocation of passwords.
- Inactivity logout.
- Explicit user roles and privilege levels.
- Biometric authentication.
- AI tracking of suspicious or unusual unauthorised user behaviour.

Data at rest



Vulnerabilities

Data at rest refers to any data or information stored with some permanence, which could reasonably be extracted or substituted, using standard equipment or intrusive engineering technique. Examples include data constants, measurement results, intermediate formulae variables, calibration tables, executable firmware, etc.

Mitigations

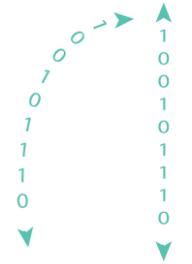
Such sensitive data, residing in some form of memory storage, presents a serious breach risk of unauthorised data access or a means to tamper with device behaviour.

Mitigations

The simplest and most robust mitigation is to design a system that keeps as much rest data as possible on-chip, whilst locking down all external read access or debug ports. Data should be kept within the boundary of a chip package, with no means to read it out via a pin protocol. This would present an extremely difficult barrier to access without highly specialised knowledge and equipment. Given enough energy and funds, it is possible to peel open a chip and probe internal data via an electron microscope. But even then, chip technology exists, especially specialised crypto key management chips, to defend against such attacks and destroy data at point of intrusion.

The next level of mitigation is to ensure all rest data is authenticated and encrypted by the application program. Authentication is a form of signature or hashing check, verifying that it is an intentional data set; it is trusted data that has not been corrupted or inserted by an unauthorised agent. Encrypted data is unintelligible without access to a decryption key.

Data in transit



Data in transit is transported within a device, or between the device and data ports or other computer systems. Within the device, data moving between electronic subsystems and the microprocessor chip may also be called 'data in use'. Data may also be in transit within the full device ecosystem, for example streaming data between the device and an external network or cloud.

Vulnerabilities

Data in use traverses subsystem chips, on industry standard digital busses, such as I2C or SPI. The data can be easily probed or manipulated with standard engineering know-how. Data can be stolen, or sensor readings can be spoofed to alter device behaviour.

Data in transit on a network connection, wired or wireless, is vulnerable to traditional eavesdropping or tampering, or a full denial of service (DoS) attack. The full networking security mitigations presented by commercial smart devices, IoT, and Cloud solutions are beyond the scope of this article. However, a designer must be aware that mature cybersecurity technologies already exist in this area and employ them appropriately.

The most ubiquitous low power wireless link, Bluetooth Low Energy, already contains pairing authentication and data link encryption, which when used following the correct guidelines, can also be validated for medical device use.

Mitigations

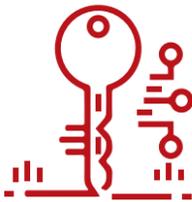
Data should always be encrypted while in transit, preventing data from being intercepted to be stolen or manipulated (falsified).

To prevent eavesdropping of the data transfer, its encryption must be →

'end to end': between an electronic subsystem and the microprocessor chip, or between the device and a peer network machine's processor. Anywhere a data analyser can be placed on a data path, it must return only encrypted 'unintelligible' data.

Data 'end' points should also be mutually authenticated to ensure they have not been substituted or faked. Typically using digital certification, or, on an embedded device with a challenge-response protocol (exchange of a common secret, also encrypted).

Encryption key management

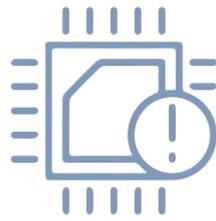


Best practice encryption utilises known published 'strong' algorithms, such as AES, which require secret key(s) (akin to a password) known only to the data provider (encryptor) and data consumer (decryptor). The encrypted data is only as secure as the 'key length' (akin to number of required password 'guesses') and the secrecy of the keys.

By example, NIST recommends an AES key length of 256 bits (AES-256), which will outstrip hacking compute power (continuous 'guesses') for the reasonably foreseeable lifetime of a device manufactured today.

Then the key itself needs to be secured. Essentially, any key emplacement on a device needs to be placed in a non-discoverable or probeable memory or specialised key-store chip. The line of risk stretches from design through to manufacture and in-field support. Mitigations to maintain secrecy are both technical and procedural; such as minimising the number of people that come into contact with full clear keys.

Firmware



A medical device will contain application specific executable code, which performs the device functions in close harmony with the electronics design. Its integrity is fundamental to the behaviour, safety, and security of the device. The executable code and datasets are permanently emplaced in the device build, and this is known as the 'firmware'.

Vulnerabilities

Software will always contain bugs. A bug is a fault in computer code which causes it to run contrary to intended design, resulting in unexpected behaviour or results. Bugs represent a significant cybersecurity risk, they have the potential to expose critical data or a means to accessing or deriving critical data. With the best test will in the world, bugs are always going to be present during a product's lifetime, when tens of thousands of units could be in use.

The risk of errant software is further exacerbated by the increasing trend of code reuse and 3rd party libraries (SOUP). Increasingly, in addition to the main application processor and code, a device may also have additional microprocessors and firmware for dedicated peripherals such as smart sensors or wireless comms protocol stacks.

Software development tools rely on debug channels into the application microprocessor. Third party SOUP items may also support instrumented debug modes, 'back doors', and default passwords. Hackers could access all of these functions to gain full access and control of a device. Alternatively, a hacker could seek to replace entire code units, which can be a surprisingly trivial exercise for known common

hardware platforms. Once trojan software is installed, a device could be repurposed for unauthorised (unsafe) use, stored data can be accessed, or systems and users could be tricked into revealing data.

Finally, any accessible data port is potential point of access to internal software and data. Using known or disruptor protocol patterns, a hacker could provoke a run-time error that disables security measures or reveals data.

Mitigations

Software safety

- Code firmware packages should only be distributed in encrypted form and stored encrypted if located in off-chip memory.
- Firmware should be authenticated prior to execution, to ensure it is approved software and has not been tampered with.
- Remove all logical and physical debug channels at manufacture (e.g. JTAG).
- Test, test, and test software prior to deployment to discover as many bugs and weaknesses as possible (IEC 62304 provides a framework for focussing software test coverage).
- Engage the services of a 3rd party Penetration Test facility to uncover device vulnerabilities and seek expert advice as early as possible in the development cycle.

Maintenance

- Monitor and assess customer reported bugs.
- Monitor SOUP items for bugs and vulnerabilities, using supplier bulletins and known vulnerability databases.

Upgrade and revocation

- Provide means to remotely revoke or disable a (connected) device.
- Provide means to securely upgrade any firmware item on the device (ideally remotely, upgrades via physical access could be prohibitive in cost).

Glossary

AES	Advanced Encryption Standard. De facto data encryption algorithm, as adopted by US government agencies
Cloud	A networked application or data storage resource, hosted via the Internet
DoS	Denial of Service. An attack which floods a network with traffic, causing it to crash
Embedded	Embedded software that runs on a microprocessor and controls non-PC electronic devices
Firmware	Same as embedded software, usually permanently stored on a device in read only memory (ROM)
IEC 62304	A standard specifying the life-cycle process for the development of medical software, harmonised by the EU and US
IoT	Internet Of Things, a set of interrelated networked computing devices
JTAG	Joint Test Action Group, in software engineering refers to a standardised hardware debug port
MMI	Man Machine Interface, an operator control interface posed by a computing device, or GUI when contains a graphical interface
NIST	National Institute of Standards and Technology, plays a respected and leading role in defining and approving cryptographic systems and electronic security
SoC	System-on-a-Chip, a single hardware chip comprising a microprocessor and specialised hardware functions. Akin to an application specific computer
SOUP	Software of Unknown Provenance, a term used in medical software to describe imported 3rd party software that was not developed to recognised medical grade software compliant processes

Conclusions

Cybersecurity resilience starts from the ground-up, when considering the system design of a medical device. All sources of critical data, and their data flows, need to be analysed and designed for safety. Exactly the same as established risk and hazard analysis, this needs to be an ongoing activity, through the full design cycle, manufacture, and in-field maintenance and support. Effective cybersecurity cannot be delivered as an after-thought or 'bolt-on'.

As medical devices become connected, and more complex, and software content continues to substantially increase, this can present a formidable task to managing cybersecurity. Fortunately, the anticipated (5G accelerated) 2020 growth explosion in industrial, transportation, and construction IoT devices will offer a lifeline to the complex development of connected medical devices. Most

IoT and connected medical devices share a common architectural platform and are constructed from the same hardware and software components. The increasingly necessary support that manufacturers provide to enable IoT security is directly transferrable and leverageable for medical device construction.

Establish a security architecture, and then explicitly review and select a supplier system-on-chip platform which meets these needs, with a longevity to match your medical device life. This may also include the increasing vertically integrated pre-secured supplier offerings, such as mobile reference applications, cloud infrastructure, or chains of trust for device firmware upgrades.

The growth of software reuse and homogeneous hardware platforms is, however, a double-edged sword. The same information and development

“Cybersecurity resilience starts from the ground-up, when considering the system design of a medical device. All sources of critical data, and their data flows, need to be analysed and designed for safety.”

toolkits enabling developer productivity are also available to the hacker community. Designers must be prepared to counterbalance the hacker effort-reward with time and effort spent securing a system. Cybersecurity is not free, it must be included in development plans, it comes at a cost.

Once a device has been designed to be secure, it needs friendly test before being released into the hands of potential hackers. Do not just test individual secure functions do what they do, a device needs objective security testing across all access points with any and all tools and knowledge available to hackers. Again, with the growth of IoT and connected devices, the availability and access to testing frameworks and cybersecurity penetration test and technical security assessment services is on the increase.

A device can never be guaranteed 100% secure. Code size and inspectable and testable permutations is ever increasing, any data path can be probed or spoofed, and any chip can be potentially removed or replaced. Managing cybersecurity is an exercise in risk management, it is about closing as many doors to the hacker as possible, and providing a level of low risk acceptable to customers and end users. ENDS

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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