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MDET

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Paul Lee
NAMDET Editor

Happy New Year

BUT WHAT SHOULD WE DO WITH THE OLD ONE?

So that was 2018. And a big thank you to anyone and everyone working tirelessly in the NHS and celebrating its 70th birthday. NAMDET is 7 years old and the year culminated in our annual conference in Birmingham's National Conference Centre with a wide range of speakers, not only celebrating achievements and new initiatives, but also taking time out to look back and forward in equal measure. This edition of MDET covers a number of the key subjects giving a summary of the presentations as well as asking us all to look back a little, learn lessons and look to the future to see how we can all improve and embrace change.

When I started in the NHS back in 1986, Bananarama were in the charts with their rendition of 'Venus' and Nick Berry was number one in the UK charts and his video appeared on BBC's Top of the Pops, a programme which was the highlight of Thursday evening TV for me.

Back then It took the BBC almost 3 days to get the programme ready as the charts were officially issued on Tuesday lunchtime, after collecting the sales figures by motorbike courier from a selected number of shops from across the UK. Today that would take a click of a button, and very cheap software (which would also include analysis of people's spending habits) and would collate all sorts of data, interpret and graphically show which song was number one, separately showing the manually purchased figures from the downloaded versions via the internet and other streaming platforms.

In early 2018, Iceland Ltd. issued a notice that by 2023 it will ban plastic for its own brand products as the world begins to see the environmental damage. Rivers and oceans are piling up with man-made debris and pollution and this is causing harm to many breeds of animals and creatures. Over 40 other suppliers of plastic containers, including drinking straws, have followed suit as this new focus on what we use, and what we throw in the rubbish bins, starts to gain momentum.

The NHS and our suppliers have for decades developed clean technologies, improved ways to sterilise and decontaminate our products, make them easy to use and easily disposable. But, I wonder if we really look at where these 'used' devices go, where do they end up? The true cost is not only to develop, manufacture and distribute, but also how to dispose of them safely and cleanly.

My first ever part-time job, aged 10, was a milk round, getting up at 5 a.m. before school. All we had was single pint sized glass bottles and one slightly larger that contained sterilised milk. Gone are the days of glass milk bottles (gold tops, silver tops and red tops) and carrying 10 empty bottles; 5 in each hand and trying desperately not to drop any of them. I'm not sure if there are many milkmen still delivering and I can't begin to think how difficult it would be to carry the 4 and 6 pint plastic cartons bottle (weighing 4 and 6kg) for the average 10 year old! Milk bottles were washed and reused and re-use was promoted by collecting and returning, for a small deposit, glass pop bottles too.

It is estimated that over 15 million infusions of drugs and fluids are administered every year in the UK and that figure is over a decade old. The plastic bags, and lines and syringes and adapters, and connectors must somehow be disposed of and/ or incinerated and/ or buried in the ground. I wonder if between 2019 and 2023 we will start to see a more focussed NHS in this area that perhaps hasn't been as high on our agenda, or part of our pre-assessment questionnaires (PAQ) or business plans and 'whole life costs' as they should be.

In May 2018, the launch of a new GDPR (General Data Protection Regulations) asked us all to look at what data we collect, and where we keep it, and of course what we do to dispose of it safely too. Whether it's paper, electronic, on video tape or CD then we now are asked to record, document its location and its disposal in equal measure.

We are all responsible for what we keep, and what we use and how we dispose of it. Governments can legislate, organisations can write policies and procedures to assist and implement training courses to help share messages. But it's people that do, it's the people that act, and people that affect change.

2018 also saw some landmark inventions with the use of 3D printed replacement parts such as cochlear implants and jaw bones for our NHS patients in Wales. These highlight the amazing technological advances that are possible with plastics and materials and how application of design and materials has come so far in just a few short years.

NAMDET's close friend Steve Logan MBE, South Wales Fire and Rescue Service and the 'Blazing to Serbia' charity came to the annual conference in November and shared his personal journey and very touching experiences of reusing and re-engineering old, unwanted NHS devices, including beds and mattresses and old equipment. His work provides a poignant example how the 'throw away culture' of some parts of the UK can be re-focussed into good causes and of course cost effective re-use of medical devices too.

Steve shared images of old beds in hospitals in Serbia and how the staff cut up wire mesh from the perimeter fences and nailed it to the wooden bed frames to make new springs. An old village fire engine, that was written off in a car crash, was kept for spares such as tyres and batteries and of course fuel too. I wonder if a culture that has very little, and no real concept of the technology that we see every day, will always remain resourceful.

Do we always think twice before throwing away and replacing as there is a new feature that we haven't had (and may not actually need) whilst we strive for the latest and the best? Maybe we need to reflect on the whole life cycle of devices when we purchase new? We need to look at the whole life costs, the disposal of the data, the disposal of the batteries and the chemicals we need to clean each device, the plastic and the components , how we recycle and re-use, and if possible re-allocate to someone else that can use and benefit from the remaining years that the device will no doubt still be operationally acceptable.

I wonder whatever happened to those old IVAC 531 infusion pumps, the 'Manley' Ventilators, and 'Boyles' anaesthetic machines. Were they sold for scrap, reused, re-allocated or simply thrown in the trash? And what about the old 'Graseby MS16a' and 'MS26' syringe drivers? The UK had over a 90% install base and every hospital had them; an estimated 40,000 devices. My step-dad has one, and uses it to feed his tomatoes with BabyBio plant food - after all they have a battery life of over a month and this is a rechargeable battery too. Its over 27 years old and will probably last another 27 too.

I'm sure I speak for my technician and engineer colleagues when, like many of them, I am unable to throw out things and keep parts and components for that 'just in case I'll need one' or 'this will come in handy' trait that I/ we all seem to have. Only last week I repaired the microwave oven at home with a micro switch that I kept from over 15 years ago. The replacement was identical and fitted perfectly. I knew it would come in handy (just didn't know when or what for) and not only did it save me a fortune on a new microwave but also gave me that huge satisfaction that we get from turning around a broken device, back into a fully functioning device that we've become so reliant on.

I mentioned the music charts earlier and perhaps this provides another good example of re-use. Gone are the days of the 7 inch single and 12 inch plastic LP records… or so they say … as sales topped 4.1 million in 2018 and that's the highest sales figures since 1991. The difference here is that although this music medium is also made from a plastic material it is less likely to end up in buried in the ground, or in the oceans and more likely to end up being passed on to your children and grandchildren in an attempt to encourage them to listen to bands that you liked to listen to that shaped you as individuals. For Christmas, my youngest daughter, at 16, bought herself a record player, and now plays all my old Vinyl records including my 1977 copy of Disco Fever, 'All Mod Cons' by the Jam from 1978, and my mint 1981 copy of 'Dare' by the Human League, and her own copy of 'Can't Touch Us Now" by Madness from 2016. No doubt she'll have many years enjoyment and use out of these and will hopefully pass these onto her children and these will continue to be used and cherished in equal measure for many decades to come.

GONE ARE THE DAYS OF THE 7 INCH SINGLE AND 12 INCH PLASTIC LP RECORDS... OR SO THEY SAY ...

LOOKING FORWARD INTO THE FUTURE

This year's NAMDET Annual Conference was held at the National Conference Centre in Birmingham. Another high attendance heard an excellent array of presenters discuss challenges and solutions in the medical device sector as well as have the opportunity to engage with the sponsors in the exhibition hall. MDET writer Claire Read provides some key highlights from this year's agenda…

PATIENT PROGRESS

As Paul Lee opened this year's NAMDET Annual Conference, the organisation's chair was reflecting on a stay in hospital – and the need to celebrate good medical device practice during challenging times.

Shortly before this year's NAMDET Annual Conference, Paul Lee found himself taking on a new role at the hospital at which he's worked for 15 years – that of patient.

As medical devices training manager at Abertawe Bro Morgannwg University Health Board, Mr Lee has trained hundreds of staff in administering intravenous medications. But suddenly he found himself on the receiving end of care.

"I've never had an IV in my life but three weeks ago, I was sent in by my GP with suspected sepsis and it was the early stages," Mr Lee, who serves as chair of NAMDET, told delegates. *"I spent six days in hospital, I had almost fifty intravenous infusions and being a patient, I can tell you, is a very different experience. I was on the receiving end of care that I teach people how to do, so I saw it completely differently."*

> "I'VE NEVER HAD AN IV IN MY LIFE BUT THREE WEEKS AGO, I WAS SENT IN BY MY GP WITH SUSPECTED SEPSIS"

Sometimes there was cause for concern – case in point, *"the night nurse practitioner that told me she doesn't wear gloves and didn't like using an IV dressing strip to hold the cannula in place".* But the first thing Mr Lee did on returning to work was to pen an email to the director of nursing and ward manager praising the exemplary approach of one individual.

It was a very conscious decision, he told delegates; a recognition that staff are often working in less-than-perfect circumstances, and that praising good practice is as important as calling out problematic practice.

"Today's healthcare is incredibly complex," he said. *"It involves people and processes and systems and, miraculously, it all seems to work despite what the papers will have you believe.*

"There's an old saying that says that the people in the NHS are the best resource that we have. That's not true. They are the only true resource that we have because without them, we have devices that can't operate themselves. We have nothing."

And, he reminded conference attendees, many are currently experiencing challenging times. *"Today's NHS is fast-paced, working at high pressure and in sometimes unhelpful cultures with high rates of stress. It's really hard for all of us to work safely."*

He continued: *"The safety of our patients is dependent on the people that interact with them and those members of staff being physically, emotionally and psychologically well. We need our staff to be safe in their workplace, to feel supported and encouraged, rewarded and thanked and cared for. It's sometimes nice to be told you're doing a great job and how much you contribute to the organisation."*

It's that spirit, he said, which informs one of the major developments NAMDET is planning for 2019 – a bursary scheme, *"to help support outstanding NAMDET individuals in their professional career, and to promote the practice across the UK".*

And in the continuing advance of NAMDET, he saw plenty of reason for positivity. *"Little did we think that we would make such progress in just seven short years, so NAMDET would go from a small group of 12 likeminded individuals, to what is fast becoming the envy within the healthcare profession, not just in the UK but we have members from America, Belgium and France."*

And so he offered thank yous to every delegate. *"Thank you for your hard work. Thank you for your commitment to improving everything we do. Thank you for supporting NAMDET."*

"We are the NHS resource," he emphasised, *"no matter how many millions of pounds we spend on devices".*

PRESENTING CREDENTIALS

It's been a long process, but the Life Science Industry (LSI) Accredited Credentialing Register is now officially live. With it comes the promise of a simpler way of managing the ethics and safety of NHS interactions with industry representatives, as Andrew Davies explained.

In 2017, the clinical lead for the nascent Life Science Industry register addressed the NAMDET Annual Conference and made a bold prediction. *"In 12 months' time,"* said Dr Michelle Dawson, a consultant anaesthetist at Derby Teaching Hospitals NHS Foundation Trust, *"the register will either be flying or on its knees – which it's going to be, I really don't know."*

The answer, it transpires, lies at neither of those extremes. Since launching in March, initially in a pilot phase, the register has been making slow but steady progress. It was the voluntary nature of the undertaking which had left Dr Dawson unsure what the future would hold: it is not mandatory for those in the life sciences industry to add their name to it. But come the 2018 NAMDET conference, 110 already had, with 700 more in the process of signing up.

Andrew Davies – director for market access at the Association of British HealthTech Industries, one of the bodies collaborating on the register – said the vision behind the project was a straightforward one.

"Credentialing is, basically, all about getting through the front door of a hospital from an industry perspective. It's about the checks and balances that go on to make sure the industry personnel that go into these settings know how to behave in those settings and understand the responsibilities they take on by entering the premises, by interacting with staff, and sometimes with patients."

The idea of credentialing for life science industry representatives originated in the United States, he explained, but the register very much constitutes a British twist. *"In the US, there are probably 12 to 15 companies that perform credentialing services, and these are appointed on a group by group basis."*

Mr Davies argued that this constituted a worst case scenario for the NHS, since it would mean one company operating for one hospital to one set of criteria and another in another using a completely different set.

"What's happened in the US [has] meant [credentialing] is actually a cost of about $1 billion per annum to industry. Many companies actually have to employ departments to manage credentialing, to manage all of the training records, manage the badges etc.

"On one hand we thought: 'That's good. It raises standards, it's focused on patient safety.' On the other hand, we went: 'Yes, but it's a huge bureaucratic burden and it's costing money. We don't want to have to pass costs on to the NHS'."

Enter the register. Initially conceived about four years ago, it secured the backing of then-NHS England medical director Sir Bruce Keogh. *"We agreed the NHS and industry would work together to try and develop a national scheme,"* Mr Davies told delegates. *"It would very much be around supporting safe joint working between the industry and the NHS. So we set out to develop one national scheme, one set policy."*

A key requirement on the part of the NHS was that the register have a degree of independent governance. This has come in the form of the Professional Standards Authority (PSA). *"These are the people who govern the statutory registers, such as the GMC [General Medical Council] and NMC [Nursing and Midwifery Council],"* explained Mr Davies. *"They also have the remit from government to accredit non-statutory registers, with healthcare science being an example of one of those."*

The developed scheme covers all healthcare and pharmaceutical industry representatives, and has a strong code of conduct coupled with a fitness to practise element.

"It sets standards for training and education, for anyone who is on the register. It will be validating appropriate training courses, there is continuing professional development and maintaining your status on the register, and there is a disciplinary process as well. So very much like a doctor can

> "WE AGREED THE NHS AND INDUSTRY WOULD WORK TOGETHER TO TRY AND DEVELOP A NATIONAL SCHEME,"

be struck off from the GMC register if they do something really bad, equally, someone can be struck off from this register as well."

Mr Davies explained the register sets out standards in three key areas. *"Standards of proficiency – so, do you know what you're talking about? Standards of conduct – do you say it nicely and politely? Standards of continuing professional development – do you maintain the standards?"*

Precisely what those standards cover will depend on the individual seeking to join the register. *"We realise that industry is a very broad church, so you range from people going in [to NHS institutions] selling from catalogues into procurement, to people supporting very complex interventions in a theatre environment.*

"We didn't feel that it was a one-size fits all approach that was required here. We basically split things into three tiers. Tier one is you have nil interaction with patients, you're not in any patient-facing areas, up to tier three, where you are in highly sensitive areas – ITU, paediatric wards, theatres etc."

The register has an open, public face via its website – *"so at any time, any member of NHS staff can go and check the basic information about who is on it"* – but NHS IT is also being embraced. Anyone on the register is issued with a card, which contains a standard barcode. At hospitals with barcode scanning equipment, knowing if someone is on the register and at which tier will be as easy as scanning said card.

Clearly the interest shown so far in the register has been encouraging, but Mr Davies says those involved in the project are working hard to encourage continued momentum. *"There's an implementation team from the NHS point of view, they've been synchronising through the academic health science networks and we are putting a letter through the [NHS England] gateway process to announce [the LSI register] further to NHS chief executives."*

And so perhaps by this time next year, the team will be able to report with full confidence that the register is flying.

To view the register, apply for individual membership or simply find out more, visit **lifescienceindustry.co.uk**

A NEW REPORT

Sarah Jennings is optimistic a new national patient safety reporting system will make a real difference to medical device safety – not to mention a committee specifically charged with improving clarity around important alerts.

When Sarah Jennings speaks of NHS Improvement's approach to medical device safety, she describes a few separate aspects. *"We have, really, a three pronged approach: to increase our understanding of what goes wrong in healthcare; to enhance our capability and capacity of managing things that go wrong; and to tackle major underlying barriers."*

A key tool in that approach has traditionally been the National Reporting and Learning System (NRLS), set up in 2003 to serve as a central database of patient safety incident reports.

As the new patient safety clinical lead for medical devices at NHS Improvement, Ms Jennings is specifically charged with using the NRLS to uncover new and under-recognised issues. But there's a realisation that the system is no longer quite up to the task.

"With all due respect, the NRLS is a historical beast and has been going for over 12 years," Ms Jennings told delegates. *"It's very focused towards acute NHS organisations, large hospitals. It doesn't have a great deal of capacity for GP practices, dentistry, other community areas at all, and there is limited opportunity for feedback." Ms Jennings also questioned whether NRLS really meets everyone's current and future needs?*

"We have to take that on board, and we have to provide something new for the future that maximises transparency, learning and gives that robustness to prevent the overlapping functions and allows you to fill it in and you can get on with your day job."

National bodies are hoping that 'something new' will be the Patient Safety Incident Management System (PSIMS). This successor to the NRLS, it is intended to make it easier for both patients and staff to report safety issues and, in turn, make it easier for national teams to interrogate the data and spot trends.

"It offers us an opportunity to use modern technology and improve the health service for patients, so that all reporters can get on with what they need to do, in working towards patient safety," explained Ms Jennings.

She added: *"Once completed, we envisage this system will allow the NHS to meet our statutory duties to collect and analyse information about what has gone wrong, and to provide advice and guidance about how to reduce risks. [As well as] to provide a better understanding about what goes wrong, and to support increased transparency, and that's part of the 2017-19 business plan."*

The system is currently in beta phase, with a group of organisations having volunteered to test it during this period. It is hoped 2019 will bring the full go live of the system. But it is far from the only development intended to bolster the ease with which medical device safety issues can be identified and then addressed. Ms Jennings explained the Department of Health and Social Care has also announced support for a new patient safety alert committee.

"This is responsible for ensuring the NHS can clearly recognise alerts and communications that do require absolute urgent action to protect patients from the most serious risks, and that's regardless of the issuing body," she said.

A review conducted with the Medicines and Healthcare products Regulatory Agency (MHRSA) had indicated the need for such a body, she said. *"We looked into all the different types of*

[safety] communications that go to the organisations. So, you get the bulletins, alerts, safety communications, recalls. They're all named slightly different things, and they're all asking organisations to provide something, and it can be very confusing.

"There are many different styles, and it was noted that organisations are often unsure of how to determine the importance of each alert. In addition, there are over 100 alerts that come through CAS [Central Alerting System] just in a year.

"So the review looked at what people want, and there was a clear drive for prioritisation and understanding of what is expected of organisations and how they want to show compliance and safe practice without, obviously, straying too far away from the alert."

The idea is that the committee – which is being chaired by new national patient safety director Aiden Fowler, with Care Quality Commission chief inspector of hospitals Ted Baker as deputy chair – will cut through some of this complexity.

"[The idea is that] future alerts that do require complex manoeuvres to meet them will stand out," explained Ms Jennings. *"The CQC is then going to monitor the compliance of specific national patient safety alerts as appropriate during they inspections. So it's a much better, joined up approach."*

She was keen to stress the committee is not just another approval mechanism for safety warnings. *"It's more like an endorsement or a kitemark for any alert."*

And she was also quick to emphasise that any reporting or alert system is only as helpful as the related and resulting actions that are taken. For manufacturers, it is a case of ensuring that device design takes into account known problems.

"Sadly, we do see repetitive themes of device or consumable recall based on things like choking hazards, the integrity of the device, parts coming off it, lack of awareness about that.

"So it's really important for device design to incorporate all of those as a basic specification for medical device design. Caps should be tethered, so they're not going to come off. Ports should be moulded as part of a device, and guidance clear with respect to the integrity of that device. There are really good systems to try and enable safety, but it would be very much more useful if industry could take on board that basic specification too."

She continued: *"Manufacturers can try to work within that basic safety specification, and clinical human factors groups can help design to make sure you get a device that does what we want it to do. Clinical procurement teams can therefore drive selection of those devices among the huge amount that are out there. Hopefully, we might get to a stage of what can't go wrong, won't go wrong."*

Learning was absolutely the operative word in all work around device safety, she suggested. *"We do use medical devices, and they do often result in unattended and unforeseen harm, but we have to learn from those incidents in order to shape medical device safety in the future.*

"Learning is the key thing here, so learning from the incident itself, learning from devices and surveillance within the industry, and also learning from a greater understanding of human behaviour and interaction with devices, and in the workplace."

There may be lots of work to be done to get the new Patient Safety Incident Management System fully up and running – not to mention for the new national patient safety committee to bed in – but in concluding her speech Ms Jennings described the future of medical device safety as *"rosy".*

"We have a new reporting platform, we have a defined alerting system, and we have both acknowledgement of procurement and clinical human factors moving forward. Also, the RCN [Royal College of Nursing] 2020 clinical competencies document will reflect on a number of medical device procedures, which is great.

"Let's hope that by having this joined up approach that we can influence and offer frontline users reproducible system solutions for the future."

> IN ADDITION, THERE ARE OVER 100 ALERTS THAT COME THROUGH CAS [CENTRAL ALERTING SYSTEM] JUST IN A YEAR.

HSIB
HEALTHCARE SAFETY INVESTIGATION BRANCH

Improving patient safety at a national level

NAMDET Annual Conference

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A NEW INVESTIGATION

The Healthcare Safety Investigation Branch (HSIB) has only been in existence for 18 months but, as its head of safety intelligence told delegates, the hope is that it's already making a difference.

Farnborough has long been home to two organisations charged with reviewing serious incidents. The air accidents investigations branch and the rail accident investigation branch sit side by side, their staff seeking to understand why things have gone wrong and how they can be prevented in the future. A year and a half ago, the Hampshire town became home for another similar body, intentionally modelled on the previous two: the Healthcare Safety Investigation Branch (HSIB).

The HSIB formally came into being on 1 April 2017. But Tracey Herlihey, its head of safety intelligence, told delegates the body's roots can be traced back to an academic paper published in 2014. *"It was written by Carl Macrae [of the Centre for Patient Safety and Service Quality at Imperial College London] and Professor Charles Vincent [of the department of experimental psychology at the University of Oxford] and they wrote about the downfalls of the NHS having independent inquiries, and starting afresh with each new inquiry."*

Ms Herlihey gave the example of the 2001 review of the higher than expected rates of deaths among children having heart surgery at Bristol Royal Infirmary – the recommendations of which were echoed by the report into failings with maternity care at Morecambe Bay 14 years later.

Explained Ms Herlihey: *"Teams are often short lived and dissolved after the inquiry, and there's no real capacity to review progress against the recommendations. [These inquiries] are rare, they're costly, and conducted often years after the event – so if we look at the most recent inquiry around Gosport, it's looking at an event that happened many, many years ago."*

And when it comes to how incidents are investigated at a local level, there have also been challenges. *"They're often investigated by members of staff in a trust,"* pointed out Ms Herlihey. *"Staff in the trust who have a full time day job as well, and they're taken away from their day job to kind of conduct these investigations."*

The conclusion, she says, was clear. *"The whole system around how investigations are conducted within the NHS needed a bit of a shake up."*

It's come in the form of the HSIB, an initiative recommended in Macrae and Vincent's paper. The body currently sits under NHS Improvement, but operates independently and legislation is currently going through parliament which will make it a fully-fledged arms length body.

Some 12 investigators are currently in post, with a range of experience. *"So, they have clinical backgrounds, they've come from air accidents investigation background as well, military backgrounds and some have had experience in doing investigations in marine and so on, and in human factors."*

The branch is primarily responsible for conducting national investigations; up to 30 a year across any NHS funded care in England. But Ms Herlihey said that a secondary remit is to *"improve the standard of investigations at a local level as well".*

"So we're not only conducting our own national investigations but eventually we hope to improve [all] investigations and the system within which those investigations are conducted at a local level, even in a hospital."

And when it comes to maternity, the branch is actually taking full responsibility for all investigations. *"In November 2017, the secretary of state for health and social care asked that we take on all maternity incidents across the NHS in England,"* explained Ms Herlihey.

> THE WHOLE SYSTEM AROUND HOW INVESTIGATIONS ARE CONDUCTED WITHIN THE NHS NEEDED A BIT OF A SHAKE UP.

"There was then a request made that we actually replace all maternity serious incidents [investigations], including maternal death, which we estimated to be around 1,000 incidents a year. So, since this time last year, we've been recruiting over 100 maternity investigators to be able to conduct those investigations, so we're currently rolling that out around the country and hope to have that fully ironed out by April 2019."

They may be the new kids on the Farnborough block, but HSIB is certainly hitting the ground running – and its team hoping they can create a new, improved investigations process which benefits NHS staff and patients alike.

WHERE WE STAND AND DELIVER

11,000 MEMBERS OF STAFF

Establishing just how many members of staff need training, at which points, and on which devices, is a challenge which will be familiar to many medical device educators and trainers. Tanya Szczygeilski detailed how she and colleagues at a Birmingham trust had gone about meeting it – and the challenges that remain to be overcome.

When Tanya Szczygeilski joined Heart of England NHS Foundation Trust as a senior educator, she admits to feeling a little overwhelmed at the scale of the task in front of her. The organisation – now merged with University Hospitals Birmingham NHS Foundation Trust – ran three hospitals, a chest clinic and community services.

"That equates to just under 11,000 members of staff all in all and our clinical staff equate to just over 9,000." Yet, in a situation which was likely familiar to many of those listening to her speak, the medical devices education team was small. She knew some prioritisation was needed if a robust programme was to be put in place.

"When I joined the team, it took a little while for me to get my head around the vast array that is medical devices," Ms Szczygeilski reported. *"But what was clear to us was that we really needed to establish our core list of equipment so that trust staff knew who they could approach should they need training on a particular device."*

Step one: a scoping exercise to determine which devices were easily accessible to staff from equipment libraries, and so most likely to be used. *"The intention [was] should staff be able to easily take a device from our equipment library, then they should also know who to speak to to actually gain support and training if required on those devices,"* Ms Szczygeilski explained.

Step two: working out for which devices there was a training need, and how urgent that need was. *"There is a list of core devices that is found within each equipment library on each hospital site, and we wanted to scrutinise that and look at this a little bit further. So, we used our risk rating to be able to fine tune where our attention would be.*

"We also wanted to look at which devices may be addressed by other teams. So we quickly removed the patient-controlled analgesia pumps because they were looked after very well by the pain team. Anything to do with beds, mattresses were looked after by our tissue viability team, so we removed those.

"Then, in the interest of making sure that our focus was appropriately guided by high or medium-risk equipment, we removed our attention from the low risk equipment so we could focus on the others. This gave us a list of core devices – with the addition of medical gas safety; this was raised as a risk within the medical gases committee, and with the rationale that gases are pumped or utilised via the use of medical devices, that sat with us as well."

Being crystal clear on what training the medical devices team could, and should, offer made it possible to develop a portfolio of training opportunities for staff. The approach is a blended one. *"We provide face-to-face training, particularly useful for our high risk devices and e-learning opportunities.*

"[We have] an awareness that it is very difficult at the moment in many cases for staff to be released from a clinical area to attend training. So where our resources allow, we will actually go to the clinical area and support training as required to enable staff to be able to deliver high-standard safe care with regards to medical devices."

But about 18 months ago, the trust chair asked a sensible question: how did the team know they were training enough people?

"We were constantly trying to beat our quarterly training numbers," remembered Ms Szczygeilski, *"but were we actually delivering what was expected? Were we not delivering enough on certain devices?"*

That's when the team decided to investigate developing a training need analysis setup. With limited resources, it was key to find ways to use existing systems *"to ensure we still had time as a team to continue training provision".* And so Ms Szczygeilski reviewed two electronic platforms already in use: e-learning setup Moodle, and learner management system Easy Learner.

"Utilising these two together, we've been able to produce a training needs analysis that is remotely managed, supported by us as and where is necessary, but is something that we can do remotely which enables us to continue to train and respond to the feedback that we receive."

Staff are invited to complete a training needs analysis on an annual basis via Moodle. When they log in, they see the list of core devices in use at the trust. They identify the equipment they are currently using, and are then asked to identify if they are competent in its use.

"We did create the possibility that staff would be concerned about saying that they're confident to use a device for fear of repercussions if, after that moment of completing it, an error occurred. So, to try and support that potential issue with it, there are a number of modules within the training needs analysis itself which provides educational support and resources for staff.

"So if they were determining whether they were able to use wall oxygen for example, but they say: 'Well, what is the criteria for competence? Am I competent? I think I might be, I'm not sure,' then they would be able to have a look at the resources and determine from that [what they knew]."

While the training needs analysis sits within the e-learning platform, it 'talks to' the learner management system. It is this cross referencing which makes it possible to identify when a staff member needs to complete a specific training programme – a traffic light system is used. *"Staff are prompted with e-mails and their managers are also copied in, so the managers are aware of what they have or haven't completed."*

> WHEN I JOINED THE TEAM, IT TOOK A LITTLE WHILE FOR ME TO GET MY HEAD AROUND THE VAST ARRAY THAT IS MEDICAL DEVICES,

At first glance, the overall results gave cause for optimism. *"We're very pleased to say that the majority of it is green and that is demonstrating that we are training sufficient numbers of staff according to those who have identified within the TNA that they do need training."*

But it is not entirely mission accomplished. *"I was very pleased with the red dot system: 'Great, that's helping with compliance, we're getting a steady completion through each month, that's great.' However, we now realise that we've only had 60% completion of the TNA, so we're looking at over 40% of staff who still haven't completed it. I've been able to look a little bit further into core staff groups that aren't completing it, and we do need to address that moving forward."*

The numbers also show that, of those who have identified training needs, only 28% have actually accessed training. *"We need to find out the reasons why,"* said Ms Szczygeilski. *"We need to speak to managers and divisional leads and target those who need to complete training as a priority. We need to look at the course bookings and we need to look at them on a monthly basis."*

While the situation might not be as strong as the data originally suggested, Ms Szczygeilski said the value of knowing that simple fact is incalculable. *"So, it's not as good as it originally looked, but this is what we need to know for a system to be used properly and to actually drive forward high standards and make sure that patients are receiving correct care."* It's another sentiment which many colleagues will share.

WORKING ON **THE BOOK**

At Abertawe Bro Morgannwg University Health Board, a new workbook is helping ensure staff remain competent on one of the highest risk categories of medical device.

Paul Lee is frank when it comes to the potential dangers of intravenous therapies. *"By definition, when we look at our equipment management, there's no question, intravenous infusions and IV therapy is classified as a high-risk clinical procedure,"* Mr Lee said.

"The machines that we use for intravenous therapy are high-risk devices. They're on people's databases as high risk devices."

Mr Lee – medical devices training manager at Abertawe Bro Morgannwg University Health Board and chair of NAMDET – was no less frank on the need for continuing assessment of an individual's IV competence.

"It's not just a case of: 'You need to be trained and competent to give IVs.' You need to demonstrate your ongoing competence as well."

That reality, he explained to delegates, threw a huge issue for his organisation. *"We asked all our nursing staff, through a show of hands over a period of a year: 'When was the last time you were assessed giving an IV?' The record was 31 years, so it had been 31 years since someone had been reassessed giving an IV.*

> "YOU NEED TO DEMONSTRATE YOUR ONGOING COMPETENCE AS WELL."

"Don't tell me the practice, and products, and procedures haven't changed in that time, because they have massively. It's clear within all government guidelines and NMC documentations, you need to remain competent."

And so in an effort to ensure increased rigour in the health board's IV training, Mr Lee and colleagues have recently introduced a new workbook. Staff must successfully complete it before they attend the practical IV study day. *"They fill the workbook in with the help of a manager on the ward, or a mentor, and they come on a study day.*

"There are prerequisites for this training which include completing all 12 sections of the workbook, which is brand new for 2018. It's got 12 chapters ranging from legal and professional accountability, right through to anaphylaxis.

"They have to do an online aseptic non-touch technique course, and of course anaphylaxis, and we test them for maths as well. So they read the workbook, and they get supervision right throughout the sections. They're not expected to do this on their own, because we have mentors, 52 mentors across the organisation, to support them."

Mr Lee believes the IV workbook and its supportive training programme is unique in Wales. *"It's taken us years to develop it and we as an organisation are prepared to share it across the UK."* Because, after all, there will be no organisation in which IV therapy and related devices are not a high risk area.

PASSPORT TO **CONSISTENCY**

Gezz van Zwanenberg is on a mission: to make device competencies consistent across North West London. It's hardly a simple undertaking but, he told the NAMDET Conference, progress is already being made.

If you've worked in a newly-merged trust and been faced with the headache that is introducing standardised device competencies, spare a thought for Gezz van Zwanenberg. As a nurse at the North West London Critical Care Network, he operates across 25 separate intensive care units.

Each uses different devices and, as Mr van Zwanenberg pointed out, there are huge advantages to being equipped to use equipment not currently in use at one's primary place of work. *"I might quite like to be able to use two or three different types of infusion devices. That allows me then to have mobility, it allows me to pick and choose where I work.*

"And it might be nice for me to be part of a rotational process that allows me to gain experience in different areas. At the moment, the barrier is often the equipment or the training or the governance around those two subjects in an organisation. And we have a ridiculous situation whereby I as a clinician, as I move from one organisation to another, have to redo a huge amount of training."

The exception, he noted, was advanced life support. *"I walk in, I show my ALS certificate, and I can defib any patient. No one says which defib did you train on, because it's part of a standard framework."*

His dream is to have something similar in place for all types of medical devices across North West London. The means, he hopes, will be the Clinical Applied Skills Passport (CLASP). The first step – IVs.

"In London, we've managed to get all 52 ITUs to agree to one competency. It's eight pages long. It's based on the theory, so it requires the critical care nurse to have some other building blocks in place, including a trust competency IV."

The idea is a to reduce variation in training and skill within North West London, provide central basic competencies, and reduce repetition of learning. But fundamentally, Mr van Zwanenberg told delegates, it's about patient safety.

"For me as a clinician, the whole purpose of me doing anything, either at work clinically or if I'm going to work on a project, it's got to have a patient safety influence."

> AS I MOVE FROM ONE ORGANISATION TO ANOTHER, HAVE TO REDO A HUGE AMOUNT OF TRAINING.

LET'S GET SOCIAL

When Darren Maskrey joined the Midlands NAMDET group a couple of years ago, he wanted to find a way of keep in touch with colleagues between meetings. And so he turned to LinkedIn.

"It was the first place I went to try to look for a forum where communication could take place, sharing best practice, just sharing anything positive to do with medical devices, training, anything like that, really. So we set up a LinkedIn page for the Midlands group."

Mr Maskrey, healthcare development for ConvaTec, is also now at the helm of the recently-established NAMDET Facebook page. He is encouraging all members to follow it – as well as to consider connecting on LinkedIn, and perhaps setting up their own pages for their regional groups.

"It's a great way of just raising the profile of NAMDET and just sharing information with each other," he concluded.

THE DIGITAL REALITY

When Maria Bramwell asked delegates to put their hand up if they owned a mobile device, every single one did. It was an indication, suggested the clinical training lead at GE Healthcare, of the extent to which digital has changed our day-to-day lives – and the need for that change to be reflected in medical device training.

"Technology has changed the way that we work. And evidence suggests that students who have face-to-face and digital learning will actually have higher achievements in their learning."

Fellow presenter Heather Young said her experience had borne that out. The medical devices and staff development lead at Nottingham University Hospitals NHS Trust worked with staff at GE to provide training on new anaesthetic machines. As well as in-person learning, there was an e-learning component.

"The advantages of the digital training is our staff can acces it wherever." She said the other benefit is that it gave her and her colleagues *"a huge amount of oversight".*

IS THE FUTURE MADE OF VIRTUAL REALITY?

For Jack Pottle, the use of digital in device training could go way beyond online learning and into virtual reality. The medical director at Oxford Medical Simulation spoke to delegates and demonstrated his company's products in the exhibition area. *"We create virtual reality medical simulation so that people can perform as in real life, be that doctors, nurses, anyone in the clinical environment,"* he explained.

"And the focus is on interaction with that patient – it's clinical decision making and critical thinking to be able to do the actions they would do in real life and then face the consequences of those actions."

Many delegates were intrigued, and no doubt already thinking of the many possible users of the technology for device training.

LOOKING BACK AND MOVING FORWARD

AS WE VENTURE INTO THE NEW YEAR WITH RESOLUTIONS A PLENTY I THOUGHT IT WOULD BE A GOOD THING TO LOOK BACK ON WHAT AFPP AS AN ORGANISATION HAS ACHIEVED THIS YEAR AND ALSO WHAT I HAVE PERSONALLY EXPERIENCED THROUGHOUT 2018.

It has been another strong year for the organisation with us supporting many collaborations, new initiatives and projects across the sector. Everything we do as an organisation has to support safer surgery, so when we are asked to support a professional committee such as NHS England and their work around NatSiPPs, the Institute of Decontamination Sciences and the orthopaedic instrument Survey, Skills for Health and the development of the ODP Apprenticeship, we are always happy to do so as we feel these initiatives are important to patient safety and to the practitioners who work within this area of specialism.

On a personal level, I have been struggling with knee pain for around 18 months and after three consultations, two X-rays and an MRI scan (no partridges or pear trees!) I spent a lot of soul searching and opted for an arthroscopy which went ahead on 19 November at the Nuffield Hospital Leeds. I had the privilege of being part of the commissioning team for the hospital back in 2011 and saw it grow literally from the ground up. The fact that I was familiar with the hospital did make things more comfortable. Is there an opportunity here to encourage hospitals to have regular open days so patients can see first hand the facilities prior to being admitted for their care? Or could a walk around/ familiarisation to the environment form part of the pre-op assessment visit? Just some random thoughts/ideas.

I cannot begin to tell you how different it is to be on the receiving end of the perioperative experience, particularly knowing how much I do about never events and patient outcomes. It didn't help either that I was speaking at the Quality Improvement Safety Training (QIST) day in Newcastle the week before my operation. The speaker before me used patient experience videos to support his presentation; they were about two patients who had undergone knee arthroscopies and had both experienced deep cavity infections and how this had devastated their lives. A debate then took place around whether prophylactic antibiotics should be given to patients undergoing this procedure. There were two very compelling arguments for and against and I listened intently to the arguments as I was keen to glean what was best for me. Ultimately, it came down to hospital policy and it turned out that the Nuffield policy was not to administer prophylactic antibiotics as a matter of course.

My continual questions during my consultations led to my consultant asking, 'do you work in the industry?' and I very proudly told him what my role was, and I waxed lyrical about what AfPP stood for and our role in supporting perioperative practitioners. He listened patiently and when I had finished he responded, 'I have spoken at your conference in Harrogate in the past'. So he was very much aware of what we did, and he was very mindful of our importance in the perioperative arena. Which I was really happy about.

When the day came for my operation the team at the hospital were great, very personable and followed the 'hello my name is' mantra well. There wasn't one person that I met who didn't introduce themselves. As a patient I felt very valued and felt very comfortable from the outset of my journey through my day case procedure. The anaesthetist and consultant visited me in my room, as you would expect, and the list started on time and I was first up. I initially thought this was preferential treatment but now realise that the quicker cases are put at the top of the list so they can be worked through quickly and if there are any complications the least cases as possible are cancelled.

I walked the short distance to theatre and my chaperone chatted to me, making me feel very much at ease. Now I am not a novice at this sort of thing, having had hip resurfacing, a hernia operation etc., but I do get a feeling of anxiety as I enter the anaesthetic room, that 'what if feeling'. I always joke about it with my family – if I don't wake up don't worry I've had a happy and fulfilled life. I am guessing these thoughts go through everyone's minds in a situation such as this.

Anyhow, I climbed up onto the table and the gentleman assisting the anaesthetist immediately told me he was a member of AfPP and how valuable he found our services. This was extremely reassuring to know as I felt it meant he valued our goals and objectives around supporting patient safety. Very important when you are on the receiving end of surgery. Obviously, most patients would not have these checks and measures to be able to monitor practice by and I feel privileged to be able to do so.

At the point of writing this article my outcome has been very good, less pain and very mobile from the outset. Sitting doing nothing for a number of weeks was very difficult for me as I am a natural 'doer', so my husband has struggled to keep me sitting and only doing the exercises suggested by the physiotherapist.

I was in fact well enough to travel to London three weeks post op to chair a discussion around fires in theatre. There was representation from the Interim Director of Nursing policy at the RCN, the Education and Standards Committee from CODP, Patient Safety Lead from NHS Improvements, Head of Policy at the Patient's Association, Infection Prevention Lead at 3M, the Patient Safety and Quality Lead at AfPP and an Insight Consultant at APCO, the company representing BD with this project.

Following the discussions, it was clear that there is agreement that this is a serious issue which is preventable and urgently needs to be addressed. It was also clear that there is a strong will to work together to find a national joined-up approach to finding solutions. The plan is to develop a short life working party to develop a strategy to create positive change.
So AfPP will start 2019 with a new project and will continue to develop new, practical ways to support our members and patient safety.

May I take this opportunity to wish you all a very happy, fulfilled and safe New Year.

Dawn L Stott
Chief Executive, AfPP

Dr Matt Fogarty
Deputy Director of Patient Safety (Policy and Strategy), NHS Improvement

Help us develop a national patient safety strategy for the NHS

Last month we launched a consultation on proposals for a national patient safety strategy that will support the NHS to be the safest healthcare system in the world. We are keen to hear from readers of the MDET Journal what they think, including any further ideas for us to consider for a final strategy.

In this article I've briefly summarised our proposals, but you can read further detail in our consultation document at https://engage.improvement.nhs.uk/policy-strategy-and-delivery-management/patient-safety-strategy/.

Our proposals for a national patient safety strategy

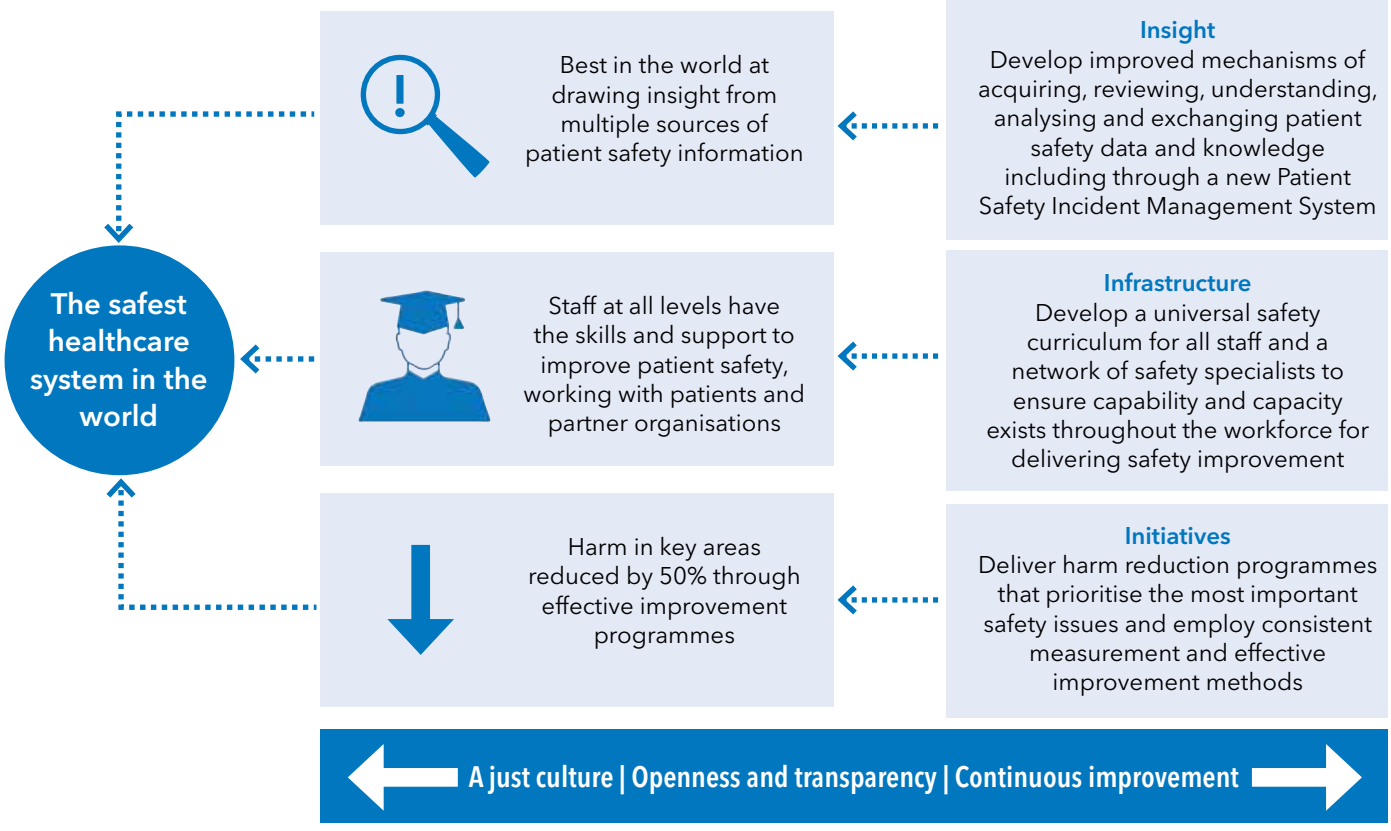
Our consultation proposes three core aims for a national safety strategy.

These are for the NHS to:

- be world leading at drawing insight from multiple sources of patient safety information
- give staff at all levels the skills and support they need to help improve patient safety so they can be the infrastructure for safety improvement, working with patients and partner organisations
- decrease harm in key areas by 50% by 2023/24 and beyond through specific patient safety initiatives.

We have also highlighted three principles that are fundamental to delivering safe healthcare for patients and that should underpin implementation of the strategy: a just culture, openness and transparency and continuous improvement.

Figure 1: Our proposed national patient safety strategy



An NHS-wide patient safety curriculum

Two major components of our proposals that we would like input from MDET Journal readers on sit within the **Infrastructure** priority area.

Firstly, we think it is time to develop a consistent curriculum for the training and education of all current and future NHS staff in patient safety. We want this new curriculum to be used from boards to wards so that all NHS staff have a good understanding of safety and can use that knowledge to support improvement in their day-to-day work. We would like your thoughts on whether this makes sense, what this curriculum could contain and how it could be delivered.

We also believe that improving patient safety requires certain individuals across healthcare to have a high degree of skill and understanding to enable them to lead safety improvement efforts. Therefore, we are proposing to create a network of patient safety specialists in providers and other organisations who can be the backbone of patient safety learning and improvement across the NHS.

We aren't suggesting these roles need to be filled by recruiting new staff, but rather we think the NHS can identify existing staff who are already working in safety-related roles, be they nurses, doctors, pharmacists, managers or allied health professionals, and who can be supported to become these skilled specialists. Your views can help us shape these roles

Improving insight

Another of our proposed priority areas, **Insight**, incorporates NHS Improvement's statutory patient safety functions under the Health and Social Care Act 2012. These are to collect information about what goes wrong in healthcare, which we primarily do currently via the National Reporting and Learning System (NRLS); and also to use information from incident reports and other sources to develop policy and provide advice and guidance - which is primarily done through Patient Safety Alerts.

Our consultation sets out how we want to further improve the way that we fulfil these duties so the NHS can become the best in the world at drawing insight from multiple sources of patient safety information.

Much of the work under this priority area is already underway, such as the work to develop the new Patient Safety Incident Management System as a successor to the NRLS, and the creation of the National Patient Safety Alerts Committee. We do still need your input to develop these areas further however.

Patient safety initiatives

Under our third priority area, **Initiatives**, we propose committing to reducing the amount of harm caused in key areas of patient safety by 50% by 2023/24 and beyond.

We know that measuring harm and patient safety is very challenging and so we are not suggesting a universal 'target' for safety improvement overall. But we also know that we can define objectives for safety improvement in specific areas as long as we establish good measurement strategies focussed on clearly described issues.

We think we should be prioritising programmes to tackle issues where the most significant harm is seen, litigation costs are highest, unwarranted variation is greatest, and evidence-based interventions are known to mitigate risk. To choose and prioritise these programmes we would be guided by experts such as professional associations, royal colleges, frontline clinicians, patient representatives and the Patient Safety Translational Research Centres. Do you agree?

The main route for delivering these initiatives would be the Patient Safety Collaboratives (PSC) programme. Our recently commissioned review of the PSCs recommends their continuation but with a more consistent and structured approach. A key part of this will be better alignment with the seven NHS regional teams that are being created as part of NHS Improvement's and NHS England's commitment to integrate regional structures.

Tell us what you think

We have based our proposals on what we have learned from the engagement around the NHS Long Term Plan, the Care Quality Commission's (CQC) review of Never Events, the work to review the Serious Incident framework, and the Gosport Inquiry and other inquiries such as those at Mid Staffordshire NHS Foundation Trust, and University Hospitals of Morecambe Bay NHS Foundation Trust. We have also used insight from CQC's inspections and state of care report that highlights safety as the most significant concern across the NHS. However, we recognise that a system-wide effort will be needed to deliver our ambition. Therefore to ensure we end up with a strategy that is the right approach for all parts of the NHS, be that physical or mental health care, in or out of hospital and primary care, we are looking to hear and incorporate views from a wide range of people and organisations.

If you would like to find out more and take part, visit our consultation webpages https://engage.improvement.nhs.uk/policy-strategy-and-delivery-management/patient-safety-strategy/ where you can find our full proposal document, and complete our online consultation questionnaire. The consultation closes 15 February 2019.

Your responses will help inform a final national patient safety strategy for the NHS that will be delivered from April 2019, alongside the new NHS Long Term Plan. *Thanks for your help!*

Stephen Lee, *MHRA Senior Regulatory Policy Manager*

Medical device regulations and the health institution exemption: what you need to know

The new medical device regulations (MDR) and in vitro diagnostic medical device regulations (IVDR) continue the exemption for devices that are made or modified and used within a health institution. To benefit from this exemption, health institutions will need to put in place a number of specific requirements.

Compliance is required by 26 May 2020 for medical devices and 26 May 2022 for in vitro diagnostic medical devices. During this transitional period, it is expected that organisations work towards compliance.

The NHS Confederation has produced a briefing paper, and the MHRA has also produced a simple one page outline for NHS organisations to refer to when considering how to prepare for the changes ahead.

Are you a health institution?

The new regulations define a health institution as "an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health"; NHS Trusts and Health Boards fall within that definition. Some specific collaborations may also be included.

What devices are made or modified and used in your health institution?

Making or modifying a device may include:

- **putting together a device from raw materials or component parts where this is not explicit in the manufacturer's instructions**
- **fully refurbishing a device**
- **developing new software or new diagnostic devices**
- **assigning a new medical purpose, performance or function to an existing device**
- **using a device without a CE mark for a medical purpose**

Devices that are manufactured on an industrial scale are not eligible for the exemption.

What will you need to do?

You will need to have in place:

- **An appropriate quality management system**
- **A justification for applying the exemption that is based on target patients' clinical needs that cannot be met by equivalent devices available on the market**
- **A public declaration of conformity**
- **Full technical documentation to allow understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose**
- **A system of reviewing clinical experience in the use of the device and taking necessary corrective actions**

You will need to fulfil all the relevant general safety and performance requirements set out in Annex I of the regulations. This includes requirements for devices to be designed and manufactured to achieve their intended purpose, to be safe and effective and to not compromise the safety or clinical condition of patients, users or other persons. Risks should be acceptable when weighed against the benefits for the patient.

Next steps – scoping

Senior managers in health institutions should plan for implementation of the health institution exemption. This might begin with a scoping exercise to find out how many devices may fall within the exemption. This may include 'home brew' devices, modified devices, non-medical products, research or investigational use products, off-label use of devices, and custom-made devices. Some research and development projects (including clinical trials) might also need to consider the requirements of the exemption.

Next steps – gap analysis

Once you have an indication of the numbers of products and their spread across different departments, you can start to consider the impact of the new regulations and the adequacy of your existing systems and processes. You will also need to decide what resources you will need to continue providing essential clinical services.

Next steps – implementation

It is likely that you will need to upgrade your existing quality management systems to meet the new requirements.

You should set up an implementation roadmap that clearly identifies actions and responsibilities for implementation of the changes brought by the new regulations, including gathering clinical evidence to support the use of the device now and for the lifetime of all affected products.

You should link with the medical device management committee (or equivalent) to establish defined responsibilities for action.

Senior managers should be responsible for reviewing implementation to identify any new or ongoing areas of risk.

Next steps – MHRA consultation

Prior to the final date of application of the new IVDR and MDR, the MHRA is consulting on a guidance document to advise health institutions who make or modify and use their own devices.

This can be accessed at: **www.gov.uk/government/consultations/health-institution-exemption-for-ivdrmdr**

The consultation poses several specific questions and also seeks general responses and feedback.

Alongside the consultation, the MHRA is setting up a network of UK demonstrator sites to help inform the final guidance. Demonstrator sites are being asked to share the outputs from their scoping surveys and gap analysis to help other health institutions benefit from their experience.

Collaborative Procurement Partnership
Don Valley House,
Sheffield,
S4 7UQ

18th December 2018
Email: cppceimt5@supplychain.nhs.uk
www.supplychain.nhs.uk

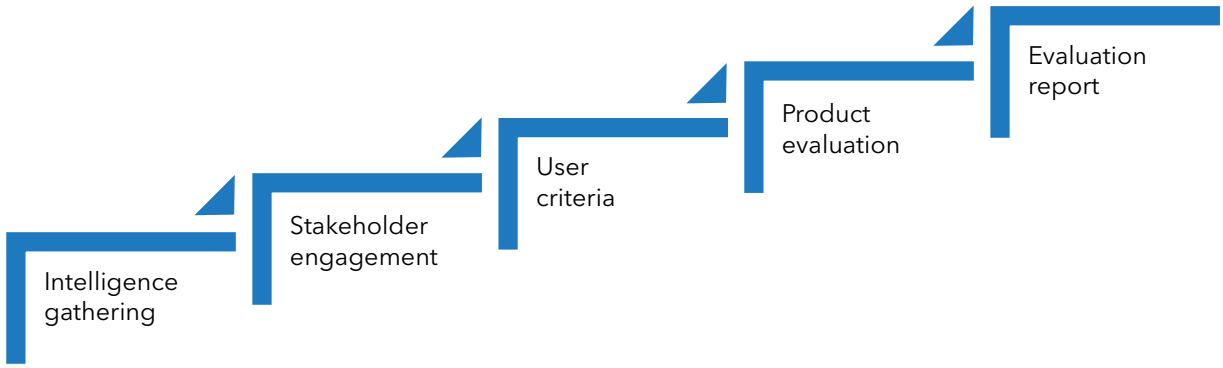
Dear Colleague

RE: Clinical evaluation of Simple Aids for Daily Living

I am writing to you on behalf of the Clinical Engagement and Implementation Managers (CEIM) for NHS Supply Chain Rehabilitation, Disabled Services, Women's Health and Associated Consumables, Tower 5 provided by Collaborative Procurement Partnership LLP (CPP).

The CEIM team members are a clinical team employed by CPP and are fundamental to delivering the new NHS Supply Chain Operating Model. The team has been brought together from a range of NHS and procurement organisations, and includes theatre practitioners, nurses with acute sector experience and paramedics. Team members have extensive experience of working in clinical procurement roles at national, regional and local levels. Our role is to develop and apply a formal and transparent process of clinically evaluating healthcare products to identify those that deliver quality, safety and value to the NHS.

To deliver this, we have developed a 5-stage evaluation process:



The results of the evaluation will be published in the format of a product report and will be published in the NHS Supply Chain catalogue.

The process will be assured by the Clinical and Product Assurance (CaPA) function of Supply Chain Coordination Limited (SCCL).

The role of the Clinical and Product Assurance (CaPA) function of SCCL is to perform clinical assurance on behalf of SCCL.

SCCL is committed to providing a clinically assured, safe and optimised product range for the health and social care system which meets the needs of Allied Health and Care Professionals (AHCP), patients and carers.

What are we currently evaluating?

All Rehabilitation, Disabled Services, Women's Health and Associated Consumables are currently associated to a national contract/framework. The following framework is being reviewed:

- Simple Aids to Daily Living;
- Crutches
- Walking aids (Walking sticks / frames)
- Commodes
- Shower chairs and stools
- Perching stools

We are keen to engage with relevant clinical staff prior to the expiry of current contracts to understand the clinical requirements in each of the different clinical settings.

How will we develop the evaluation criteria?

The evaluation criteria will be developed to ensure they are objective and measurable. They will reflect what the clinical/end users tell us they need the product to do, to ensure the delivery of care is safe, represents value for money and provides a quality patient and end user experience.

To build evaluation criteria for the products, we will run a series of national engagement activities with clinical stakeholders, including for example, workshops, individual consultations, online surveys and webinars for NHS clinicians.

We will undertake an independent review of the current literature/evidence base and, along with technical and supporting literature from suppliers, develop this intelligence into a set of evaluation criteria.

If you would like to join our national network of clinical staff keen to be involved with the process, please email **cppceimt5@supplychain.nhs.uk** with your details or those of any interested colleagues.

Thank you for your support.

Kind regards

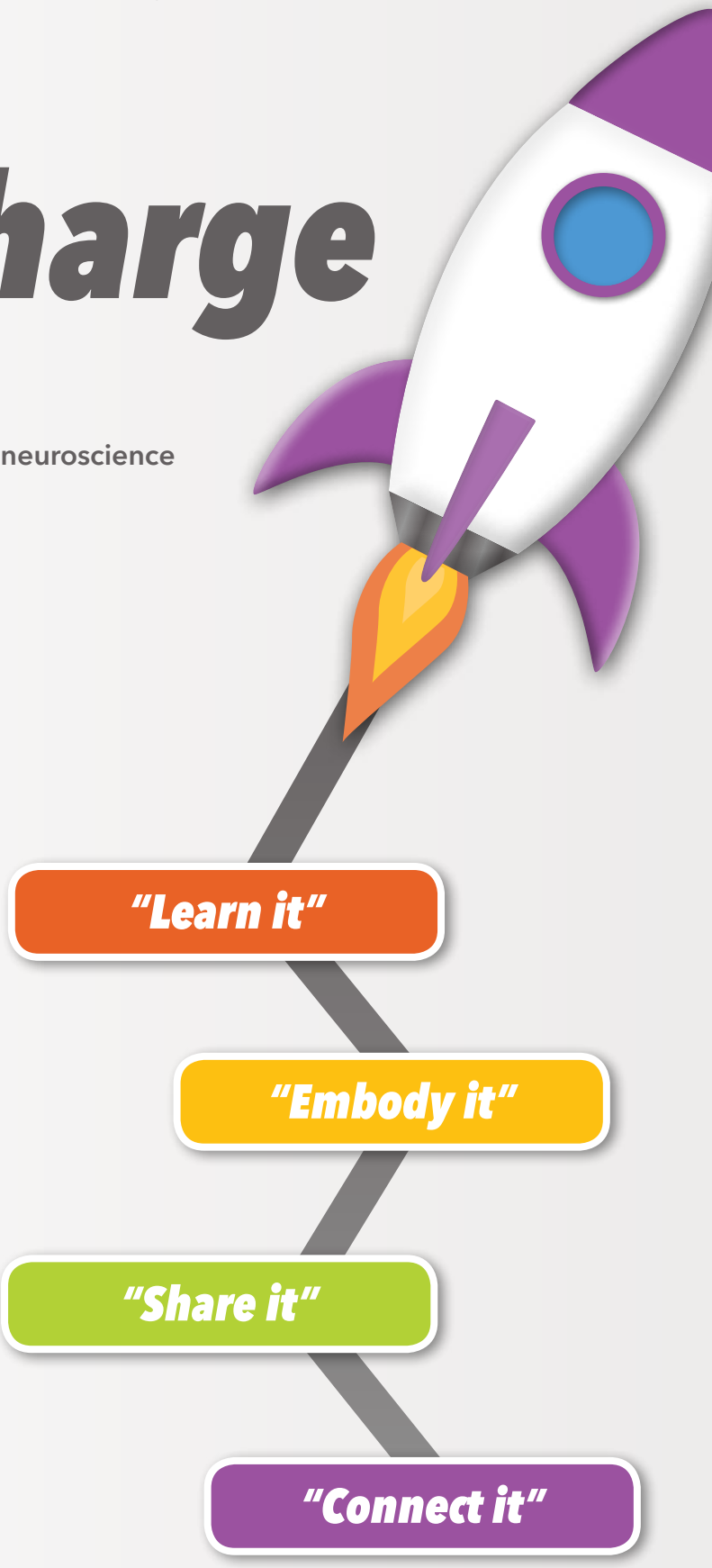
Clinical Evaluation & Implementation Team

NHS Supply Chain: Rehabilitation, Disabled Services, Women's Health and Associated Consumables.
Provided by Collaborative Procurement Partnership LLP

Article by Diane Irvine, CEO of Healthcare Skills International

Turbo-charge your training

How to boost your education courses using neuroscience and brain-friendly techniques



Our brains have a tremendous capacity to learn – take in new information, apply it/make a behavioural change or store it to use in a later situation.

However, the capacity of the human brain is not limitless, especially today, when we have so much easy access to news and information in an instant. We are often bombarded with interesting yet irrelevant information competing for our attention. As a consequence, our brains may put up blocks even to the information and skills we really need, leaving learners still *"UN-aware, UN-informed, UN-motivated and ultimately UN-trained"*.

There is a plethora of learning methods available. However, putting the brain of the learner first makes the most sense, especially in the field of healthcare.

We all, typically, have a set of key neural structures for taking in new information, storing it and enabling long-term behavioural change.

In essence, a brain-based learning cycle involves:

- **Providing new information at an optimal pace and manner for the neuro-mechanisms underlying learning ("Learn it")**
- **Active participation of the learner ("Embody it")**
- **Sharing of learning with other learners on the course ("Share it")**
- **And deliberate practice and application of new knowledge or skills relevant to a job, task or situation of the learner ("Connect it")**

It sounds quite straightforward and simple, and at its most basic level, it isn't that complicated – a brain is still a brain.

A neuroscience approach to training is certainly more efficient and effective than many other models, as it utilises our brains' in-built processing and retention of new information and capacity to make long-lasting behavioural changes. As a result, learners feel more empowered or *"turbo-charged"* to directly apply what they have learned to their jobs.

In order to apply a neuroscience-based training approach with a group of learners, trainers and educators must still take into account the developmental needs of each individual learner as well.

Careful preparation and collaboration of the planned training with the local training manager or supervisor is a must, to ensure that the activities – especially for deliberate practice – are relevant to all individual learners and their job performance needs. If a learner can't *"connect"* or apply this new learning to their own individual job or situation, it will easily be forgotten.

Learners on a training course may also be at very different developmental levels for a particular topic or skill set. The *"unaware"* learners often have a wealth of transferable skills but don't quite know how to apply what they already have to a new job or situation, and they have different learning needs to the *"untrained"*, who are completely new and curious and eager to learn all and everything.

The *"uninformed"* don't know what they don't know and may raise objections to something new and if they go unchecked can become *"unmotivated"* or even *"unavailable"* and deliberately avoid training.

It is important not to jump too quickly to a conclusion and to prepare training programmes that utilise the existing knowledge and skills of all the brains in the room to share, motivate, involve and engage all learners.

The quality of the content and the standards of the training remain high; nothing needs to be *"dumbed-down"*. Brain-friendly training techniques respect the limited time capacity of our neo-cortex and avoids both *"brain overload"* and lack of engagement.

Thus, a neuroscience-based approach enhances the conditions for optimal functioning of the key neural structures underlying learning, behavioural change and memory.

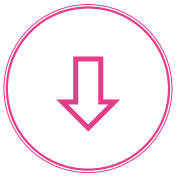
Therefore, each learner has an equal opportunity (at their own developmental level) to:

- **"Learn it"**
- **"Embody it"**
- **"Share it"**
- **And "connect it"**

… And to be in a better position to transfer their newly acquired knowledge and skills to their job, situation and life.

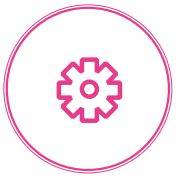
The next issue will address the necessary follow-up and evaluation of learning.

objectives



status & standing

Raise the status and standing of Medical Device Trainers and Educators



mutual support

Provide a forum for mutual support and assistance between members

represent

Represent the consensus views and opinions of members at regional and national level

inform & improve

Inform and improve national policy and the regulatory landscape by communicating NAMDET member positions on issues of importance

contribute

Positively contribute to reducing adverse medical device incidents

Selfie

Name: Mary Caddies
Age: 54
Daily role position: Lead Medical Device Trainer, Barts Health NHS Trust
NAMDET role: Management Board Member
Family (names and ages any children): Married to John with 2 children, Charlotte (21) at Newcastle University studying medicine and James (20) studying management at the University of Alabama, USA and a black Labrador called Genie
Hobbies / interests: Ski-ing, choir, tennis, gym sessions, my dog, shopping, films, TV and reading

What is your working history that led to where you are now?
I qualified as a nurse at St. Bartholomew's Hospital in 1987 and worked as a staff nurse and a renal Ward Sister for many years. As I loved teaching I took on the medical device training role in 2001 and have been doing this challenging job ever since.

What are your responsibilities?
I manage equipment training for all medical devices users at Barts Health NHS Trust

What do you find most challenging in your role?
The size of Barts Health NHS Trust – 4 major hospital sites and 16 000 equipment users

What has been your most significant accomplishment in your work?
The implementation of 'one pump fits all' for adult patient infusion pumps which included DERS

What things about your work frustrates you the most?
The lack of a national equipment training database

What do you most want those working with medical devices in the NHS to understand?
Keeping our patients safe when using medical devices is achieved by 'buy it right, manage it right and use it right'

What work related new year's resolution are you planning to make?
Introducing a sustainable and accurate equipment training database Trust wide

What new year's resolutions would you like to see the NHS make?
Due to greater financial pressures and an ageing and increasing population, the NHS model of old continues to be tested, with many questioning the long-term stability of the tax-payer funded service. I would hope that decisions made by the government and health officials post- Brexit do not put the NHS under even greater pressure. Without a deal there is potential for the supply of medical devices and clinical consumables to be disrupted.
Also, join up NHS England, NHS Improvement, Public Health England and make one NHS Headquarters.

What did you find most interesting or informative at the NAMDET conference this year?
I enjoyed the whole programme this year but I was thrilled to introduce Namdet members from the South West to each other and left them planning their next meeting with enthusiasm and excitement over lunch.

What would you like to see more of, new or topic specific at next year's NAMDET conference?
It would be amazing to have Lord Darzi as our keynote speaker for a future NAMDET conference

What changes would you like to see in the NHS relating to medical devices?
Innovation sits at the heart of the next 70 years of evolution, and embracing it is critical in enabling the NHS in England to deliver better outcomes for patients

What one piece of advice have you received that you feel has been significant to you and worth sharing with readers?
Always be kind to yourself especially when life isn't going smoothly!

What topics would you like to see covered in MDET in the future?
'A Day in the life of a Medical Device Trainer'

If you could be any fictional character who would you be and why?
Peter Pan because I never really want to grow up!

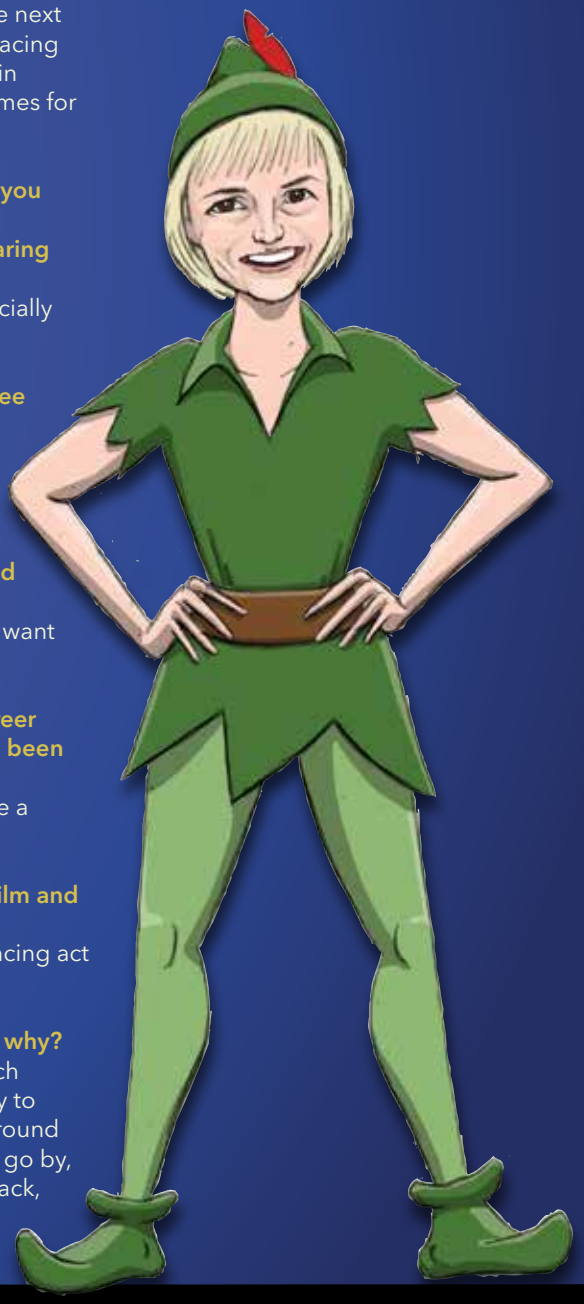
If you had not gone into the career you have, what would you have been instead?
No idea as I always wanted to be a Nurse!

What's your favourite book or film and why?
Forrest Gump – wonderful balancing act between comedy and sadness

What's your favourite song and why?
Joni Mitchell – Circle Game which tells the story of a child's journey to adulthood. It uses a merry- go- round as a metaphor for the years that go by, pointing out how we can look back, but we can't return to our past.

What / who is the person or thing that has inspired you the most and why?
Her Majesty The Queen
When bosses are looking for role models, they could do far worse than learn from the longest reigning leader of the last century.

Duty first, never grumble, do more with less, maintain your boundaries, make people feel at ease, network like crazy, play the long game and stay true to who you are, even during the anni horribili. They don't teach this at school but perhaps they should.
'It's all to do with the training: you can do a lot if you're properly trained'
Queen Elizabeth II



VOLUNTEERING FOR A LIFE CHANGING EXPERIENCE

Daniela Sabella's career has involved more than a little globetrotting – from her native Italy to the UK, but with notable trips to Cameroon and Haiti in between. Claire Read finds out more.

It was a casual chat with a colleague which started Daniela Sabella on a professional journey which would take her first to a different continent and then to the Caribbean.

It was 2012, and she was working for a private company in her native Italy, supporting the management of medical devices in public hospitals. *"I was talking with a colleague, and I told him that one of my dreams was to go to Africa and work there,"* explains Daniela, now a clinical scientist at King's College Hospital NHS Foundation Trust in London.

"So he talked with the director of the company, who is friends with a clinical engineer involved in projects in non-developed countries." And that, she says, was basically that. She soon found herself travelling to the Central African country of Cameroon, bound for a month-long humanitarian project organised by an Italian charity.

Her official title was field clinical engineer and medical devices trainer. Her main responsibility: to perform electrical safety testing on all devices in St Elisabeth's Catholic General Hospital, located in a small village to the north of the country called Shisong.

It was a big task but one she undertook with local staff, sharing her knowledge along the way. She has fond memories of her Cameroonian colleagues. *"They were approachable and really easygoing, so I didn't struggle to feel part of the team once I was there."*

Fond memories too of her fellow volunteers. *"I went with four cardiologists and three surgeons, so it was a team and we stayed all together in a lodge which was basically in front of the hospital. So in the morning we were waking up, going to the hospital, working together, coming back together, and spending the evening all together."*

During any spare time, Daniela says she would head straight to the orphanage managed by the hospital. *"I left a piece of my heart there,"* she says now.

While it may have been her dream to work in Africa, Daniela admits that when her plane touched down it all felt a bit overwhelming.

> I LEFT A PIECE OF MY HEART THERE

"Because you arrive in a country where there is nothing, and the shocking part is that everybody smiles, which is something that you don't expect," she says. *"When I went there, I landed in the capital, Yaounde, and we drove for 10 hours to arrive at this village where the hospital was, so I went through all the villages and saw how people live there."*

The journey was in an ambulance. *"Because that was the only reliable car they had."*

It was perhaps an overwhelming experience in some regards, but it was also one that ignited a passion for sharing knowledge on medical devices with those in less developed countries. And so when the opportunity came up to work for the United Nations, on a project in Haiti, Daniela seized it with both hands.

It was a different experience than the mission in Cameroon, she says. *"In Africa, I worked as an engineer, so I performed electrical safety testing on the machines, and some maintenance and then I prepared some training and some lessons for the local clinical engineers.*

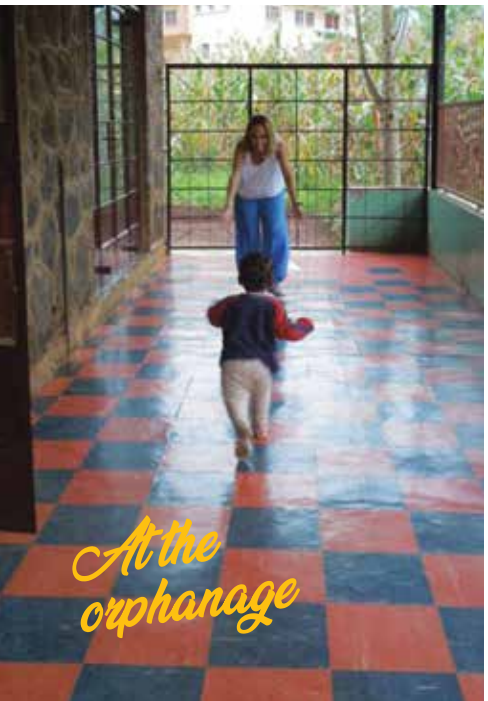
"In Haiti, it was more a managerial role. So I led a small team of logistical personnel for the opening of three hospitals. I supervised all the delivery and installation of medical devices; I was liaising with the architects and all the construction team because we needed some modification of the building to accommodate the medical devices."

By the time Daniela arrived in Haiti, it had been three years since the catastrophic earthquake which hit the country in 2010. But, she says, you could have been forgiven for thinking it had happened the day before.

"We used to drive for two hours to go from our accommodation to the hospital; there were no roads," she remembers.

The team

BOTH EXPERIENCES WERE PRICELESS FOR ME



At the orphanage

That wasn't the only reason the project was challenging. She says it took a little time to gain the trust of the local teams, and there were also logistical issues. *"When I arrived there, the works were delayed. So we had quite a few issues, because the machines were ready to come into the hospital but the hospital wasn't ready. So there was a lot of coordination and a lot of change of plans on a daily basis."*

Asked how her experiences in Cameroon and Haiti have influenced her approach to her work in the NHS – Daniela joined Moorfields Eye Hospital NHS Foundation Trust in 2014, before moving to her current role at King's in July 2018 – it's these sort of challenges that she points to.

"I think what you get from those projects is not about technical knowledge – so I cannot say I learnt something in terms of technical skills, but I improved my soft skills, like managing risks, working to strict deadlines, project management, team building, leadership."

These are all particularly valuable skills in her current role, which involves managing medical device safety alerts and safety notices. *"We investigate adverse incidents,"* she explains. *"So any time there is an incident in the hospital, we get a notification.*

"All the incidents go to a risk office, and they assign a category to each incident – green, yellow, orange and red. We investigate the orange and reds, the most serious. For green and yellow we analyse trends.

"So if we see that a green incident has happened many times, then we say, OK, there is something wrong here, and we intervene. Sometimes you can identify that there is something wrong with the training, or with the machine.

"We are in contact with MHRA [Medicines and Healthcare products Regulatory Agency], so if we feel we need to report something, we do that, and MHRA help you to investigate."

Haiti

She says it's the right time in her life to be in a settled role, but that she has certainly not lost her enthusiasm for humanitarian work in developing countries. (On reading about the Amalthea Trust in the last issue of MDET, for instance, she immediately got in touch with the charity to find out about possible opportunities to help.)

And she has no hesitation in encouraging medical device colleagues to undertake similar work. *"If you have the opportunity, just do it,"* she says. *"You have a big responsibility, because when you go there you need to have something to give. It's not a holiday. But if you really feel that you can give added value to someone in a developing country, you should do it."*

Personally, Daniella feels such work is her chance to support those who may not have had the opportunities she has enjoyed. *"I feel that I am really lucky – I had the best education I could; my parents made a lot of sacrifices to give me what they could, and I kind of feel that we have a duty to give something back. And that was my way to give something back to the community."*

She adds: *"I think the good thing about missions is that you do charity in a different way. So what African people need is an opportunity, and sharing your knowledge with them is a big opportunity, because you teach someone something and then that someone teaches something to someone else. And it's the kind of charity that stays there, it's empowering people to be independent, and that's the thing Africa needs."*

And working in developing countries immediately gives benefits for the individual too, she says. *"Both experiences were priceless for me. Sometimes you go to those missions thinking that you are giving something to someone else. And then it's just the opposite, because you come back home and you are another person."*

Hospital de Beudet

Medical devices arriving

Patient Safety Alert

NHS Improvement has published a new safety alert highlighting the risk of harm from inappropriate placement of pulse oximeter probes.

Measurement of oxygen saturation, using a pulse oximeter probe, is routinely undertaken as part of patients' vital signs during diagnosis and ongoing monitoring.

Oximeter probes can be single or multiple use and are designed to attach to specific parts of the body. Adult oximeter probes can be attached to either a finger or an ear, but are not interchangeable between these sites, whilst probes for babies and children need to be selected according to the patient's weight.

If an oximeter probe intended for the finger is attached to the ear (or vice versa), or a probe intended for an adult is attached to a baby or a child (or vice versa), it can produce a reading up to 50% lower or 30% higher than the real value.

The alert, which is available on the NHS Improvement website, asks providers to ensure staff have access to appropriate equipment and the information they need to use these devices safely.

https://improvement.nhs.uk/news-alerts/risk-of-harm-from-inappropriate-placement-of-pulse-oximeter-probes/

Actions

Who: All organisations providing NHS funded-care where oxygen saturation probes are used as part of routine or emergency monitoring of patients

When: To commence immediately and actions completed by 18 June 2019

1. Identify a clinical leader to bring together people with responsibilities for medical device training and education, clinical skills assessment, NEWS2 implementation and procurement of pulse oximeters.

2. Develop an action plan to reduce the risk of inappropriate placement of pulse oximetry probes. This should:
   - arrange for ongoing access to adult finger and ear probes in all clinical areas where oximetry is used (including for the range required for babies and children where appropriate)
   - provide point-of-use reminders on why it is vital to use the correct probe for fingers and for ears, and for babies and children
   - provide point-of-use reminders on other factors that may interfere with the accuracy of the reading.

3. Once your organisation's action plan for managing these risks has been agreed, communicate the key messages in this alert and the plan to relevant clinical staff, clinical education/training staff, and patients or their carers who self-monitor oxygen saturation levels.

MDSO and MSO Conference 2019

Medical Safety Officers (MSOs) and Medical Device Safety Officers (MDSOs) are being encouraged to attend the MDSO and MSO conference at the end of January.

The event, jointly organised by the Medicines and Health-care products Regulatory Agency and NHS Improvement will explore key themes in the patient safety arena, with a particular focus on collaboration between MDSOs and MSOs to develop synergies in meeting the patient safety agenda across all organisations.

This year's theme is effective networking and exchange of good practice in championing patient safety

Confirmed speakers include:

- Aidan Fowler, National Director of Patient Safety, NHS Improvement
- Liz Maddocks-Brown, Source4Networks and Sustainable Improvement Lead, NHS England
- Graeme Tunbridge, Group Manager, Devices Regulatory Group, MHRA

Date and Time: **Thu 31 January 2019, 10:00 – 16:00 GMT**
Location: **etc venues. 155 Bishopsgate, Liverpool Street, London EC2M 3YD**
More information: **NHSI.events@nhs.net**

CQC calls for a change in safety culture across the NHS to reduce avoidable harm

England's chief inspector of hospitals is calling for a change in culture within the NHS to reduce the number of patients who experience avoidable harm.

In a national report published at the end of 2018, the Care Quality Commission (CQC) found that too many people are being injured or suffering unnecessary harm because NHS staff are not supported by sufficient training, and because the complexity of the current patient safety system makes it difficult for staff to ensure that safety is an integral part of everything they do.

The CQC report, Opening the door to change examines the issues that contribute to the occurrence of never events and wider patient safety incidents in NHS trusts in England. The review was carried out at the request of the Secretary of State for Health and Social Care and sought to help understand the barriers to delivering safe care and to identify learning that can be applied to improve patient safety.

Based on its findings, CQC is calling on the NHS and its partners to promote a change in safety culture across the NHS so that safety is given the priority it deserves.

Professor Ted Baker, CQC's Chief Inspector of Hospitals, said:
"NHS staff do a remarkable job to keep patients safe. But despite their best efforts, never events and other patient safety incidents continue to happen. In theory these events are entirely preventable: in practice too many patients suffer harm.

"Everyone – including patients – can play a part in making patient safety a top priority and the recommendations we make today aim to achieve that. But there is a wider challenge for us all to effect the cultural change that we need, to have the humility to accept that we all can make errors – so we must plan everything we do with this in mind.

"This change in approach is essential if we are to create a just culture where learning is shared, and where solutions are created proactively to manage risk. Only then will we be able to reduce the toll of never events and the much greater number of other safety incidents."

The review was based on evidence gathered by inspectors during visits to 18 NHS trusts, and through group discussions with frontline staff, patients, and experts from other safety critical industries.

The review identifies a need for a new programme of training to ensure the entire NHS workforce has a shared understanding of their role in patient safety from the moment that they start their first job in healthcare and throughout their careers.

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