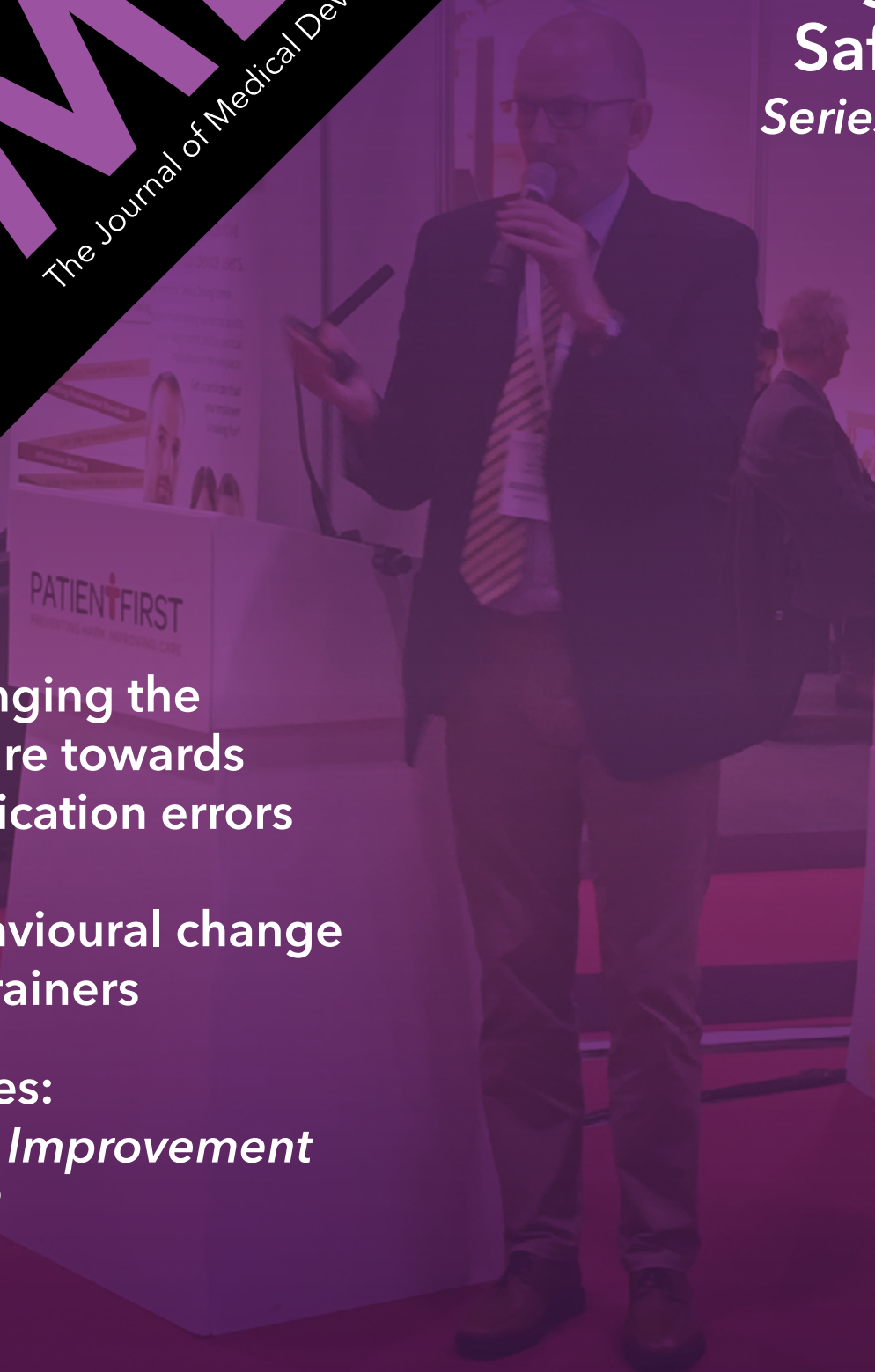**MDET**

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British Journal of Nursing, 2016, (IV Therapy Supplement) Vol 25, No 19.
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Welcome to the 6th edition of our MDET journal and a big thank you to the editorial team at Specialist Publishers for keeping up the good work, searching out those stories and keeping up the promise to grow our content and community at the same time.

Paul Lee, *Chairman NAMDET*

There have been quite a lot of changes, and updates since our last edition and i'll try and keep it brief as I know that your coffee will be getting cold and the phone will surely start ringing soon and its back to the maddening crowd and all the pressures that work and life bring.

There have been some changes at NAMDET, namely one of our original board members Mike Peel has fully retired from work after an illustrious career at the MHRA and at NAMDET too and he's enjoying time off, resting, travelling and of course relaxing with his partner and their daughter and we wish him a long, healthy and happy retirement. I have only 11 years, 4 months and 5 days, and 3 hours to retire (not that I am counting !!! :)

Our colleagues from the Yorkshire region will also know that another one of our original board members (and our conference organiser) Andy Flood has also retired and spent the last few months relaxing, planning the next stage of his life and fitting in as much course fishing as possible. We were very pleased to meet up with Andy last month and he's agreed to help out for another year (as long as we don't work him too hard) and offer his insight and experience in helping us plan and run our meetings, linking with our regions in the north of the country and acting as secretary for the new management group.

The new management team can be seen on the website and new areas of work including our new works streams for 2018 are beginning to take shape including our DERS project, CQC inspection briefing document and national competency strategy. We have a new set of templates for regional meetings including standard agenda, keeping track of key objectives and feeding into national plans. Tammy Marsh and Marie Law from the North West have invested a lot of time in making this happen, so a big thank you to the them for their hard work and sharing this with the regions.

We've managed to improve our communications this year by joining a new free teleconference service (WHYPAY) and this has been invaluable in helping us keep in touch, keep action and plans on track and of course get a chance for that all important 'chin-wag' too. This is already showing dividends and the company at WHYPAY have shared our story with others on their website. This service is free and can be used by lots of organisations, so if you're in a group, committee or need to save some money on conference calls, then take a look to see if this free service may also work for you. **https://whypay.net**

NAMDET helped run the medical device education stands at the Patient First event in November 2017, and I want to say a big thank you to the members in the London region who helped out on the NAMDET stand, to all our invited speakers, and our colleagues from the medication safety officer groups too, to Mike Peel, Mike Dixon who helped put the whole event together and also Robert Matthews, Mary Caddies and John Byrne who helped make it happen. A lot of hard work over the 2 days and a lot of effort that proved to be a great event in our calendar.

BONFIRE NIGHT.
Remember, remember the 5th of November. !!! A date for your diaries this year is our NAMDET annual conference and the theme will be focussed on 70th anniversary of the NHS (5th July 1948) and how the future may look.

Our conference will be held at the National Conference Centre in Birmingham this year, (junction 6 of M42) to give a much larger venue, better access to sponsors and a closer atmosphere for our delegates and industry colleagues. Invitations have already gone out to exhibitors and Specialist Publishers are again helping to plan and organise exhibition space, so if you need to reserve your space please contact **mikedixon@specialistpublishers.com** as soon as possible.

The NAMDET website is starting to host information about the event, (so watch that space) and a new format including invited speakers, members section and annual general meeting will be part of the new plan. We will all get a chance to vote on our way forward, new objectives and making sure that we link in closely with our members, NHS and industry alike.

On behalf of NAMDET I attended a meeting this month looking at the international picture on drug safety and infusion device management. I was amazed to learn about the healthcare structure in different countries and how difficult things can be to coordinate, plan and share ideas, resources and training. It was great to see that in the UK we are far ahead and leading the way in device training. Attendees from France, Germany and Italy were amazed that we employ medical device

I know I said I would keep this brief, so apologies if your coffee has gone cold, but I wanted to share the good news above with you and let you know that we are going from strength to strength, are getting invited to join more and more professional groups, linking in with the MHRA, MDSO network, NHS Improvement and more recently contact with the HSIB (Healthcare Safety Investigation Branch) and we can only maintain the momentum if we have your support, your help and your input. Our 5 key objectives are beginning to make sense; raising our status, a forum for mutual support, representing you at national level, informing and improving national policy and contributing to reducing incidents and errors.

2018, is the 70th anniversary of the NHS and our 7th anniversary ...... we have come a very long way in a very short time. Look where we were in 2011 and where we are now. Let's keep up the great work, maintain the momentum, spread the word and make 2018 a great year for NAMDET

trainers, have our own association and national conference too. Needless to say, we now have our first international members signed up, and they are looking forward to attending our conference in 2018 to learn as much from us as they can.

A call went out via the website to see if we could gain any interest in setting up an Irish NAMDET group and we are pleased to say that we have already had 13 names (from both sides of the border) and we are planning to meet up with the team and help set up a new regional group, which will of course be our first group to include members from Europe.

Putting Patient Safety First

Claire Read reports on recent presentations and discussions on medical device safety and putting the patient first

Time for DERS?

Infusion pump errors are common and can cause significant harm to patients. So surely software which alerts users to potential mistakes before they happen is worth implementing?

You've been working on this Word document for hours on end, and so engrossed have you been that you've completely forgotten to save it. You're about to shut your computer down, but then Word pops up with a warning box. Basic message: are you sure you want to lose this document you've been working on for so long?

It's a simple example of how software can prevent us from making a regrettable mistake which might have significant consequences. And it's a trick which medical devices are trying to repeat.

In recent years, some 'smart' infusion pumps have come with Dose Error Reduction Software (DERS) built in. The aim is to reduce errors with intravenous (IV) medications. By having a drug library built into the machine, which has upper and lower limits for doses and infusion rate, the idea is that staff are alerted before they make a potential mistake. In other words: are you sure you want to infuse this much of this drug this quickly?

For many of those working in medical device safety, such a setup will seem immediately appealing. After all, infusion pumps are a very common source of error. Indeed, Paul Lee – medical devices training manager Abertawe Bro Morgannwg University Health Board and chair of NAMDET – explained that an incident at his organisation had further convinced him of the benefits of DERS.

"The question I would hate to be asked by a coroner, which could happen to any of us, is [why was] this infusion pump incorrectly used and led to the death of a patient because the nurse put in a ridiculously high infusion rate," said Mr Lee.

"The machines have drug safety software sitting in the background but some health boards decided they couldn't switch it on because they couldn't manage it. My health board

is pressing ahead at pace because we know that on balance it can reduce risk."

Added Mr Lee: *"That's what all the published research says. The conclusions are – and this is the phrase that they use – on balance, it offers a safety system."*

So why isn't NHS Improvement mandating its use? According to David Garrett, senior pharmacist at the national organisation, it's because the picture is somewhat more complicated that it might initially appear. Yes, he said, the US Food and Drug Administration (FDA) – which controls and regulates medical devices and drugs in America – had concluded that *"on balance DERS will probably help risk reduction"*. But there was a caveat.

"The truth of the matter is research about to be published will indicate that there are errors with non-DERS pumps and there are errors with DERS systems. So any time you get a human being involved in any system, you are going to get errors. They're different errors, but it's not as though this is a clear-cut decision.

"If the research had said introduce DERS, we guarantee improved patient safety, yes, we could have an argument and a rationale for mandating. Until we understand fully what the implication is of mandating this, then we can't really go national at this point."

There may currently be no national mandate, but some organisations are choosing to plough their own DERS furrow. At St George's University Hospitals NHS Foundation Trust, for instance, all pumps have such software activated. But Dr Linda Murdoch, consultant paediatric anaesthetist at the South London trust, told delegates that it wasn't the solution to every potential infusion pump error.

"One of the things we all know is there is no one safety system that will make medication administration completely safe," she stressed. "This is one step in several different safety systems that are all required – electronic prescribing, barcode medicines administration, smart infusion technology, other safety systems within pharmacy. They're actually probably all required, but most of us don't have the money to implement them all at the same time.

"So we have, in our trust, dose error reduction software in all of our smart pumps, everywhere. We don't yet have electronic prescribing and barcoding everywhere – we've got that in 44 per cent of our organisation. And we are just slowly rolling out other safety technologies.

"I think we do have to remember that there is no one technology that will make everything safe – it is a combination of technologies. And none of these technologies are a replacement for critical thinking."

That prompted Rob Matthews, chair for the panel debate and a member of NAMDET's DERS national working group, to ask about the sort of new risks which might emerge if the software is implemented: "Is there a greater risk from picking errors – choosing the wrong drug, which runs at a different rate? And do staff become reliant on the software?

Explained Dr Murdoch: "Every drug given over a period of greater than five minutes in our institution is given via a pump using a drug library and all fluids are given via a drug library unless they're given at a rate that exceeds the capacity of the pump in resus.

"We have had some picking errors. I would suggest that we only have one to two picking errors a year reported on Datix. That doesn't mean that there are not more that are not reported, and we don't have the type of pump that is easy to interrogate. Getting information out of our pumps is not easy; there are pumps that are easier to get information out of. But I think if we had serious incidents relating to picking errors, we'd probably have the Datixs to report that."

She suggested drugs which had several entries in a pump's drug library – because of different doses, for instance – could represent a particular picking error risk. That led Mr Garrett to suggest the size of the display window on infusion pumps could be a safety risk, even with DERS in place.

"I think one of the major problems we've got is that due to the size of the window on the current pumps, some of the drug names have had to be truncated, or you've got abbreviations of the drug names. And that could be responsible for picking errors."

He added: "Nationally, we've done the research and the research base said don't abbreviate, you will get errors. Nationally we haven't got, yet, an accepted library of abbreviations or truncations. Perhaps that's something we ought to look at, and it certainly has come up in safety circles that we should have something like that."

The industry representatives on the panel stressed that they saw working with NHS staff on such issues as central to delivering good products. "We always welcome the input," reported Rachel Dixon, a qualified nurse and now clinical product and marketing specialist at B. Braun Medical. "I'm a clinician myself, and part of my role is to bring back information [from the NHS] as policy dictates."

But she reported that the display screen on an infusion pump was "a trade off game". "People also want to view the volume to be infused, volume that's been infused, pressure alarms. All sorts of other information, because we see that as reducing the risk – if you've got it displayed on the front view, you don't have to press buttons. The more times you press buttons, the more you're open to risk. So it's been very driven on this level of having displays that you don't have to touch. If we're then asked to actually increase the amount of drug names, we will lose the other details. So it's a trade off."

It was a point with which Cary Ikemoto – a qualified pharmacist and associate director, medical affairs at Baxter Healthcare – fully concurred. "As clinicians, all of us appreciate the need for a complete description as opposed to an abbreviation," he said. "But the real estate, the human factors issue, the engineering – it's challenging [to decide] what is a priority and what is not."

For Paul Lee, there were other practical challenges in the way some pumps were set up. "One of the problems with some pumps which are not that old, is that in the configuration settings you have to put in the maximum rate for a bolus. And you want a fast bolus, so you put in 1,200 millilitres per hour. And that bolus rate goes into the configuration, and that also becomes the maximum infusion rate."

He argued that the problem was that there was "no British standard which says your software must have a separate rate for infusion versus bolus. There is no British standard for drug safety software – it's left to the manufacturer to decide; it's left to market forces."

Even if it wasn't possible to mandate the implementation of a 'complete' DERS across the NHS, might it not be possible to mandate it for the drugs most likely to cause harm in the event of an error, asked Mr Lee? *"There's a survey with the medication safety team at NHS Improvement, tracking all medication errors. We know the top 10 causing harm. And yet infusion pumps, on a ward, can give insulin at 1,200 mis (mL) per hour today, and there is no trap, no safety net, and everybody in the room knows you do not infuse insulin at 1,200 mis (mL) per hour.*

"So why don't they come out of the factory with a dataset that I call DERS-lite: the top 10 drugs, we know that these cause harm, these are already loaded on to the machine, and when you use these there's a safety limit."

One challenge to such a setup, said Rachel Dixon, would be the degree of variation between organisations. *"Loading in the top 10 is very difficult, because we've built about 100 drug libraries and I can say that none of them are the same. I've never loaded a pump in a hospital and [they've] said: 'We'll have the same as them.' It's never the same."*

She continued: *"Also if you've got the 'top 10 drugs', that's in one section of the drug library and if you want to use everything else that's non drug-libraried, you have to then come out of the drug library and go into a different section, which is the mls per hour. So it means that, in effect, nurses are having to dip in between the two. And personally I feel that increases potential risk. Also, if nurses know they've got the access to the mils (mL) per hour (setting) they may just stay in those mls per hour options. Which, again, can be seen as a risk."*

For David Garrett, there were also considerations about whether trusts had the resources and expertise to implement DERS – even if it was a 'lite' version. *"I think it would be wrong, nationally, to say you must do this. I think you've got to take the onus and responsibility at individual trust level as to what you do with that capacity.*

"So the capacity could be frontloaded, and that may help you, but then I think you still need to decide whether you switch it [DERS] on or off. And that's got a lot to do with whether you think your staff are well enough trained, it's got a lot to do with whether you think you've got the problem. For example, in mental health they've come back to us and said: we don't have this problem. So it's still difficult for us to say you must do it at this stage."

He said a survey of 70 trusts by NHS Improvement had indicated a range of opinion on how much work it would be to implement DERS-lite.

"We know which are the top 10 that cause the most harm when things go wrong [with infusions]. 60% of respondents said, yes, they could implement those top 10. 18% said there would be no additional cost if we were to ask for that. And 22% said it would cost less than £5,000.

"So the survey is coming back to government and saying the cost of this is not huge. But for some, it could be – we don't know because we haven't got a full set from that survey. So we're still a little bit ambivalent about doing this, simply because the NHS has got a lot of calls on it at the moment. If it costs anything, we've got to have a rationale for the best use of that money."

There were also possible issues over the availability of infrastructure to support smart pumps with DERS, he reported. *"If you've got a drug library, and you update the library, the last thing you want to do is to be bringing all of your pumps into a central location updating it.*

"The vast majority of survey respondents, 92%, had wifi. But 70% of the pumps weren't wifi, so they had wifi available but the pumps couldn't use it."

That was a situation he felt would change over the next five years, as trusts replaced pumps and bought wifi-equipped models. And he felt that this change would also bring more evidence on DERS, allowing national bodies to give a definite line on its costs and benefits.

"I think the reality of the situation is people are going to have smart pumps. In the next five years, they're going to have the software. It seems quite sensible to use software that has a patient safety element to it. I think by natural osmosis this is going to come in, and perhaps in the fullness of time we'll know what the consequence of doing that is. At the moment, I'm not sure we can predict it with accuracy."

He concluded: *"There are errors on both sides – we know the errors without DERS, we don't really know as much about the errors with DERS. Simply because, as has been suggested, some of the pumps don't easily tell you what the errors are. So it's very early days to take such a big decision [about mandating DERS] at NHS Improvement.*

"But we're happy to help you with some of the infrastructure needs that you might have in order to implement DERS, which is probably going to happen anyway. It's likely in five years' time we wouldn't be having the question because it's just a natural consequence of evolution and improvement in science."

An Alarming Situation

Infusion pumps may have come a long way since their early days as purely mechanical devices but, as Paul Lee explains, there are further improvements which could usefully be made to ensure they are used safely.

When thinking about the devices used within healthcare, Paul Lee places infusion pumps high on his list of the most risky: *"It's an invasive device; it goes into the body. It's not like a blood pressure machine that's non-invasive. And it's active; it can make things happen to you."*

Or not, as the case may be. Because when Mr Lee and colleagues started researching the use of infusion pumps in practice, they found frequent issues meant patients were not actually getting the medication which had been prescribed for them.

"There's a therapeutic window – the drug has been prescribed for a period of time for your patient. So if you prescribe a four hour antibiotic, it's got to go in over four hours. We analysed four and a half thousand infusions, and what we discovered was that only about half of all the infusions go in as prescribed. 44% got interrupted. Some of them got interrupted numerous times," reported Mr Lee, who is medical devices training manager at Abertawe Bro Morgannwg University Health Board and chair of NAMDET.

He continued: *"The worst performing infusion was a five hour infusion that had 49 interrupts and the patient only received 19 minutes of medication. But the machine was alarming all the time, telling staff the line was occluded. They just kept restarting it, so the patient never received the medication as prescribed. There's a pharmacological issue there, never mind the fact the pump's alarming all the time and really annoying the patient and the relatives."*

He explained how another piece of research had proved that an alarming infusion pump is the soundtrack on many wards. *"We analysed two years' worth of data off infusion pumps, which equated to 21 million minutes' worth of use – one of the biggest studies ever done. And we found 1.3 million minutes' worth of alarms, going off in the background."*

Drilling down into the data showed that the most common reason for an alarm was occlusion, with one hospital recording 98,000 such warnings in one year (the study was over 2 years and this was the total number of alarms across all pumps). But there were other, less obvious reasons for alarms. One of the most notable is something you'd more commonly associate with mobile phones or laptops or tablets: a warning about low battery.

"We identified a hospital which has 7,500 low battery alarms. So the staff were informed of low battery, and 2,700 of the devices went dead. We thought the nurse had just ignored it. So we got up off our chair, and we went to the ward to have a look. And when we took a photograph of the ward, we found a metal plate with two sockets – that's it, all we've got is one for the bed, one for the nebuliser, one for the ECG machine, one for the iPad, and one for the mobile phone. Hence the machines don't even get plugged in."

It was one example, Mr Lee said, of the way in which the hospital environment can make it difficult to use infusion pumps safely and efficiently. But he suggested manufacturers also needed to make some changes to devices.

"We found 9,000 door open alarms. Which means that the nurse or patient walked up to the machine and simply opened the door while it was running. Can you open the door of a washing machine halfway through the cycle? No. Can you open the door of an infusion pump halfway through the infusion? Yes. Why? We need more manufacturers of washing machines to make infusion pumps," he said with a wry laugh.

"Every time there's an alarm, there's a delay," he emphasised. "The patient doesn't get their medication." With one device, there had been 300 door open alarms. Put another way, on 300 separate occasions a patient's receipt of a vital medication had been delayed because – for whatever reason – the door on the device had been opened.

So how can such issues be addressed? How can we ensure beeping alarms from infusion pumps are an unusual sound on the ward rather than a common soundscape? How can delays to patients receiving IV medication be reduced?

Mr Lee felt there were changes manufacturers could make to their devices that would help – making it impossible to open the door while an infusion was running, for instance. But he acknowledged that, fundamentally, it was likely to come down to better education and support for people who are using pumps.

"Research shows only 11% of errors are the machine itself," he reported. "21% is down to users, and 68% they can't work out, suggesting it could be users. So potentially, 89% of errors with infusion devices is you, not the machine."

At Abertawe Bro Morgannwg University Health Board, efforts to address that have included creating pocket cards with flow rates on. There's also an app, developed to help nurses calculate and monitor infusions.

"We've sold 30,000 copies – it's even used in Australia – and it's now been classified as a medical device and will need CE marking by The Medicines and Healthcare products Regulatory Agency (MHRA) so it can be sold as a medical device, because it's calculating something."

A nurse using an electronic pump and a mobile phone to calculate infusion rates would have been unthinkable when such devices first emerged. The early pumps were entirely mechanical, and needed to be wound up like a clock. Come the 1980s there were devices set with a screwdriver or a paperclip, and later a pump which worked on the basis of hundreds, tens and units – and on which nurses could accidentally increase the rate from 0.1 to 100.1 with one button press.

"We've gone a long way in 40 years, from the thumb wheel switches and the mechanical clockwork devices, we've got through to devices now that can sense when the syringe is missing, they can sense when the door is open," said Mr Lee.

"But they've got loads of alarms, and we have loads of delays to infusion therapy. Delays in infusion therapy, omitted and delayed infusions, is a massive problem. These machines are telling us that the drugs are not going in on time, and no one is taking any notice."

Could Dose Error Reduction Software – which tries to alert a member of staff before a mistake is likely to be made – make a difference? In part, Mr Lee argued (see separate article). *"But it will just limit the rate and limit the dose – it doesn't tell the nurse or the pharmacist this very expensive drug, costing £20K, has failed to be delivered in the time it's prescribed. That's a huge thing that's being missed at the moment."* And possibly something medical device trainers could usefully help address.

Testing times

New medications are tested rigorously before they go anywhere near a patient. But, as Tom Clutton-Brock knows, the same process hasn't traditionally applied with medical devices. Could a new centre help improve device usability and reduce risk of errors?

At the beginning of this year, what appeared to be an entirely new operating theatre opened at University Hospitals Birmingham NHS Foundation Trust. All the equipment is entirely what you would expect to see in this sort of clinical environment. Even the floor is the same. But if an expert looked closer, they would realise it does not have the specific air conditioning system required in a functioning operating theatre, and that there is no backup for the lights in the event of a power cut.

That's because there is no intention for real surgery to ever be performed in the facility. Its location – in the Institute of Translational Medicine rather than the hospital – also hints that this isn't quite a normal operating theatre. Instead, its sole purpose is to support the testing of medical devices.

"Simulation centres are very widely used for clinical training, but we've been funded to [the tune] of about £7m to build one solely to look at the usability and safety around medical devices," said Dr Tom Clutton-Brock, a clinical academic and the new centre's lead.

He explained that whereas medicines undergo rigorous testing before they are ever used on a patient, medical devices have not traditionally been subject to the same process. Part of that may be down to the sheer scale of the market, and the reality that some devices are very straightforward.

"There are over 500,000 recognised classes of medical device in Europe alone [and] 29,000 medical device companies. There are about 127 pharma of any reasonable size. The average number of employees in a medical device company in Europe is two. And their average bank balance is negative. So it's a very different financial market that we work with in terms of device production.

"The regulations are very different, and the hurdles to be crossed are very different to those in medicine. Perhaps the key thing to say is that devices are regulated and launched onto the market frequently with very little use in patients. That would not happen with medicines.

"80 per cent of the devices that you see will get into clinical practice never having been used on a patient. Many of those are because they're very simple tech and they mimic other devices. But the amount of clinical investigation that goes into devices before they're regulated is surprisingly small."

Despite this, the statistics suggest that *"devices are surprisingly safe in their own right"*. Dr Clutton-Brock pointed to data collected by the Medicines and Healthcare products Regulatory Agency (MHRA) a few years back which showed only one third of adverse incidents with devices were down to an identifiable device failure.

"Another third are down to user error, very clearly down to user error, and the other third are unknown. And I promise you that a lot of user error will be in that group as well," he said. *"Also there's huge underreporting of user error in everything that we do. If you lean back in your car, and your steering wheel comes off, you don't half report it. But if you accidentally drive into the gatepost, you don't ring up the car manufacturer and say there's something wrong with your car because I've driven it into a gate."*

Does user error with devices lead to patient harm? In some cases, the answer is a clear cut 'yes'. "Between 2005 and 2009, there were 56,000 infusion pump incidents reported to the FDA [the US Food and Drug Administration]. There were determined to be 710 deaths over that four year period from infusion pump accidents, and a very small number of those were down to to the fact the device itself didn't work.

"The most common cause of a medication error with an infusion is down to the fact that we don't use the pump correctly. And those numbers have not changed since 2004. It remains a major cause of patient harm. Despite technology, it's very unusual for a pump to run at the wrong speed; it's quite common for us to programme it to the wrong speed or put the wrong drug in it. So I believe it is a major patient safety issue."

While it is clear that in many instances harm is the result of a human failing rather than a machine issue, Dr Clutton-Brock emphasised that user error could be the result of a poorly designed device. *"I could still drive the very first car that I had*

– well, I could if it hadn't been scrapped – because the pedals are in the same place. Imagine if different manufacturers decided to swop the pedals around. Ford did actually very briefly in the 1950s produce a car in which the brake and the accelerator had been swapped around, and of course it caused absolute chaos.

"You wouldn't expect to have to go on another test to learn to use a different car because the pedals were the other way around, or if when you turned the steering wheel the wheels went the other way. And yet that's what happens in medical devices. There is very little standardisation about how things actually work across it. So it's not surprising that we get them wrong. And there's a lot of work to be done in that. There's a lot of work about usability design."

He is optimistic that the Medical Devices Testing and Evaluation Centre – which is a UK first, and run in partnership with the University of Birmingham and Aston University – could make a contribution here, by making it possible to test devices in an environment which is almost identical to a real clinical setting. Certainly he feels there is an increasing understanding that such testing is valuable.

"In the last two years, the MHRA and the FDA have both issued publications which basically say if you design new devices you must demonstrate they can be used, and they can be used safely. Your technical file will be expected to have some evidence of some usability testing to demonstrate that actually it's safe in clinical practice.

"There's an ISO standard around that – 62366 – and this says that you should do the testing in a realistic clinical environment; not in an office. You should do it with real clinical staff, not with device reps. But you shouldn't do it on real patients. So we do most of our work with volunteer staff in a very realistic environment, by using either phantoms or plastic patients, or occasionally healthy volunteers."

Even with enhanced usability testing for devices, Dr Clutton-Brock was clear that training would always be needed. *"However easy we make it to use, we're never going to get rid of the fact that you and I need to understand how to use it safely. And I don't think we can go around saying there's never any human error, it's all machine error. We're never going to get rid of everything. We still have to learn to do it; we are going to have to learn how to use things safely."*

Better connected

There are no shortage of examples of the harm that can result when a connector intended for one device is inadvertently connected to an entirely different one. The introduction of a new type of connector for intrathecal and epidural procedures, and for delivery of regional blocks, should help eliminate the dangers – so long as industry and NHS trusts get on with adopting it.

A baby lies in paediatric intensive care, with a feeding tube and a tracheostomy tube. Staff approach, ready to give the infant a feed. But a mistake is made. They connect the feed to the tracheostomy tube, and the food intended for the baby's stomach winds up in the lungs. The baby dies.

It's a horrible story, but a true one – reported in the United States in 2009. It is but one in the long line of stories of harm resulting from mix ups with connectors. Consider that a universal connector has been used for intravenous infusions, needles and syringes and also for equipment used for medications which go into the spinal spaces in your back, and it becomes very clear why such mistakes can and do happen.

"Up until recently, every one of those connectors was the same – it was a luer connector," (developed over 100 years ago) explained Paul Lee. *"So there was a possibility and there is a possibility that you could accidentally connect the connector from one of those devices to a device that you don't need to connect it to. And the only time you know that you've got an error is when the patient is harmed or, unfortunately, the patient dies as a result of it."*

To eliminate the risk, work began on developing a new international standard for connectors. But with some fearing that could take many years, an interim safety connector – Surety® – was developed, and has been adopted by some NHS trusts.

Mr Lee explained that now represented a new challenge, because the Surety device is being discontinued. With the ISO standard now available – including a dedicated connector for neuraxial devices known as NRFitTM – healthcare providers are being urged to take action. Last August, NHS Improvement issued a resource alert urging organisations to develop implementation plans for the new connector by the end of 2017.

The hope is that, by April 2018, devices for all intrathecal procedures, epidurals and regional blocks (known as NRFit) will be available to the NHS. But Mr Lee admitted that different suppliers may work to slightly different timeframes. Since different trusts start from different positions with which connectors they were using, it won't be an entirely overnight change.

In Wales, for instance, the Surety device was never adopted – only luer. And so health boards there are being urged to wait until all NRFit products are available on the market, to avoid *"moving from luer to having a mixture [of connectors] and then changing again".*

While there may be some complications to be worked through, Mr Lee argued there was no doubt the change was worth making. Ensuring that neuraxial and regional block devices could not be connected to luer connectors will cut the risk of drugs being delivered via the wrong route.

"There are huge safety risks with IV, epidural, intrathecal infusions. If you accidentally connect, you can lead to a patient death. This is very serious stuff," he stressed. *"There are new connectors from industry, they're out there.*

"And you have to plan this – you have to get teams together: clinicians and technicians and engineers and theatres and pharmacy. Everybody needs to get ready for this, because this is not going to happen on its own."
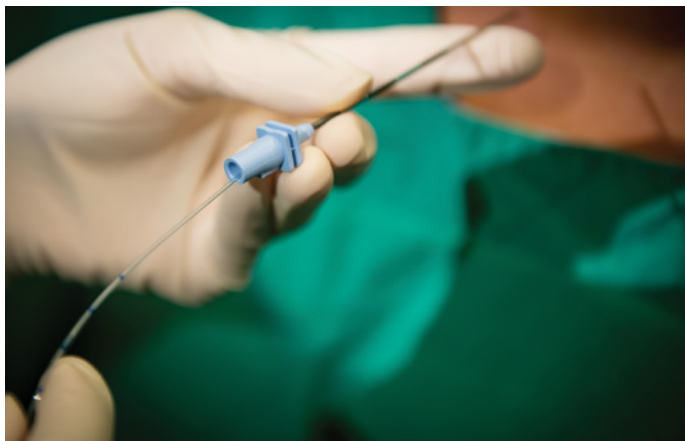
Driving an update

The Medical Device Driving Licence (MDDL) is not a new idea, but delegates heard that it is being given a new spin. Dr Tom Clutton-Brock revealed plans to relaunch the scheme, which teaches general principles on how medical devices work via an e-learning programme.

"We're trying to relaunch it and revamp it," explained Dr Clutton-Brock. "I've managed to persuade the University of Birmingham to adopt it as part of its continuing professional development (CPD) programme, which means you get a certificate from the University if you complete the course and it does come with CPD credits."

He also revealed plans to make the modules accessible on smartphones and tablets, though admitted all the work may necessitate the introduction of a new funding model.

"At the moment it's relied on everybody's goodwill to do it. I think if we're going to develop it a little bit, then I think we will have to look at having a nominal charge – probably a limited annual fee.

"What I'd like to see is many, many more thousands of users. With a relatively small income from each user, we can run the programme successfully."

He urged colleagues to share thoughts on what they would like to see from the programme via the Medical Device Driving Licence website – **mddl.org.uk**.

Perfect recall

If a product recall came into Salisbury NHS Foundation Trust, it used to take a day or longer to ensure all the affected stock was removed. But Sarah Jennings, the trust's medical device safety officer and decontamination lead, reported that had now fallen to just minutes thanks to barcodes.

The organisation is one of the six demonstrator sites for the Scan4Safety programme, which is investigating how the implementation of standardised barcodes to the NHS could save money and lives. Staff at the organisation now scan products as they go into the hospital's stock.

"We've done mock recalls since we've implemented this system to see how it's released clinical time and [ensured] better efficiency. And we've actually proved that we can manage a recall coming in to removal off the shelf in 28 minutes. That's phenomenal."

Next up, the trust plans to use barcodes to track cannula and catheter use on wards. "So staff on a ward will know how many patients have got catheters, how long they've been in and why they need them, in order to try and make sure their care is tailored specifically to them."

Almost £1m has been saved just through the introduction of scanning in cardiology and orthopaedics, she added.

Legally speaking

Derek Hamill, senior solicitor at Gilson Gray, was keen to remind delegates that their device responsibilities were grounded in the law. "To fulfil your obligation as a provider of care – or in order to ensure that you're fulfilling your obligations as a supplier of those devices – you have to to comply with the relevant regulatory framework. And in order to do that you have to make sure that your teams, your reps, the people in the theatre are all properly trained."

He continued: "You have to make sure that they're not allowing bad practices to slip in to what happens in theatre because there's never been a problem before; that there's no culture of asking if device been improperly used, because a failure leads to a claim."

Mr Hamill pointed out that the money spent annually on settling medical negligence claims in the UK had been in the region of £23bn. Fail to educate staff properly, "and sooner or later, you'll face a claim, and sooner or later you'll be part of that £23bn".

Mid Yorkshire Hospitals NHS Trust

Mid Yorkshire Trust Leverages Real-Time Location System Technology to Transform Healthcare Delivery across Three Hospitals

Overview

THE NEED

The Mid Yorkshire Hospitals NHS Trust sought to enable its three hospitals to optimise the use of critical medical equipment and improve the quality of patient care.

THE SOLUTION

After careful consideration, the Mid Yorkshire Trust selected STANLEY Healthcare's advanced AeroScout® Asset Management solution to automate the tracking of more than 2,700 assets that are an integral part of providing high-quality patient care, such as sophisticated medical equipment, beds and hoists.

As another facet of this important initiative, the Trust installed STANLEY Healthcare's Wi-Fi based Environmental Monitoring solution. Temperature tags monitor the ambient temperature of clean utility rooms to ensure medication is kept within the recommended temperature range. This satisfies the Care Quality Commission requirement for drug storage. In addition, the solution provides hospital-wide visibility into the environmental conditions of consulting rooms.

THE RESULTS

By leveraging real-time data, hospital clinical staff members now have the ability to quickly and easily locate the assets they need, enabling them to spend more quality time with patients. Additionally, the Trust has been able to decrease costs associated with replacing lost medical equipment, as its staff can now utilise convenient, online dashboards to generate real-time inventory updates.

Since the STANLEY Healthcare AeroScout solutions are Wi-Fi based, the Mid Yorkshire Trust has been able to avoid the costs associated with using a proprietary RFID network. Instead, it was able to leverage its standard Cisco Wi-Fi network to support the deployment, significantly lowering the total cost of ownership.

CHALLENGES FACED

Technology is playing an increasingly critical role today in improving clinical operations, decreasing costs, and providing high-quality healthcare for hospitals throughout the UK. At Mid Yorkshire Hospitals NHS Trust, the leadership team recognised early on the value of leveraging innovative technologies to ensure continuous improvement in the hospitals' processes

and systems, which provide the underlying foundation for high-quality patient care. This strategic commitment to quality led to a six month pilot program at its Pinderfields Hospital site to explore the use of Real-Time Location System (RTLS) technology to enhance the tracking and utilisation of critical medical equipment including: infusion pumps, bariatric beds, ultrasound equipment, mobile x-ray machines, blood scanners, syringe drivers and hoists.

SOLUTION BENEFITS

Given the importance of these medical assets in providing seamless, day-to-day patient care, the leadership team identified five key value drivers to **optimise asset management through RTLS technology** including:

1. Ensuring 24x7 availability of critical medical assets
2. Increasing productivity of clinicians and staff
3. Minimising asset replacement and rental costs
4. Maximising patient and staff satisfaction
5. Ensuring compliance with Care Quality Commission (CQC) Regulations

Mid Yorkshire Trust chose to explore the use of RTLS technology to increase environmental monitoring efficiencies and ensure temperature levels continuously remain within safe limits throughout the hospital. Given these objectives, the leadership team identified an additional five value drivers to **optimise environmental monitoring though RTLS technology**:

6. Improving day-to-day operational workflow
7. Increasing staff productivity for Medical Physics technicians
8. Ensuring the safety of items that require strict temperature ranges, such as blood, tissue, organs, medications and vaccines
9. Minimising costs associated with spoiled pharmaceuticals and temperature-sensitive medical supplies
10. Ensuring compliance with CQC Environmental Monitoring regulations

Once Mid Yorkshire Trust identified the key value drivers for their pilot program, they selected STANLEY Healthcare, a market leader in providing visibility and analytics solutions, to help them move forward with their innovative RTLS quality initiative. The two organisations worked closely together to develop the strategy for deploying STANLEY Healthcare's AeroScout RTLS Asset Management and Environmental Monitoring Solutions, and measuring the resulting impact on patient care and healthcare delivery.

"*We chose to work with STANLEY Healthcare because its comprehensive AeroScout RTLS solution helped us realise our vision to manage medical devices in a much more organised manner for compliance purposes within our Trust,*" said Dr. Alex Zarneh, Head of Medical Physics at Mid Yorkshire Hospitals NHS Trust. "*By utilising such technology, it has enabled us to significantly improve patient experience and staff satisfaction through more effective, real-time engagement. In addition we have made significant resource savings in terms of tracking of medical devices and also increased awareness of when the device leaves the hospital site with patients.*"

As a result of the initial pilot programme, the hospital's clinical staff were able to significantly decrease the time necessary to locate medical assets at the point-of care by leveraging real-time data. By eliminating process inefficiencies, clinicians could spend more quality time engaging with patients, resulting in higher patient satisfaction and better care. Additionally, the Trust was able to decrease costs associated with replacing lost medical equipment, as its staff utilised online dashboards to see the real-time location of critical medical equipment throughout the hospital. For example, before the pilot program began, clinicians found a high-value bariatric bed being used by a non-bariatric patient. After the pilot program, all bariatric beds could be tracked via convenient online dashboards to ensure they were allocated efficiently throughout the hospital.

Finally, for the Environmental Monitoring aspect of the pilot program, RTLS temperature tags were deployed to monitor the ambient temperature of clean utility rooms to ensure medications remained within the recommended temperature range, eliminating the need for Medical Physics technicians to manually record temperature data. In addition to automating the data collection process, the RTLS temperature tags also provided an early warning mechanism in the event a refrigerator lost power or malfunctioned, which decreased the likelihood of spoiled medications and temperature-sensitive medical supplies.

LESSONS LEARNED
Upon completion of the pilot program, the leadership team evaluated the resulting performance metrics and workflows based on the ten key value drivers identified at the start of the initiative. Overall, they noted significant improvements in clinical operations, decreased costs, and improved healthcare delivery at the point-of-care, which led them to approve the business case for expanding deployment of RTLS technology throughout the three hospitals that comprise the Mid Yorkshire NHS Trust: Pinderfields Hospital, Dewsbury and District Hospital and Pontefract Hospital.

The Mid Yorkshire Trust leadership team also assembled a cross-functional group of clinicians and staff from its Medical Physics, IT and Pharmacy departments to discuss the best ways to facilitate wide-scale deployment of STANLEY Healthcare's AeroScout Asset Management and Environmental Monitoring Solutions without negatively impacting the day-to-day, operational workflow of the hospitals. The transformational RTLS quality initiative was completed in the spring of 2015.

The leadership team at Mid Yorkshire Trust is committed to leveraging innovative technologies to improve the workflows, processes and systems that are critical to providing high-quality patient care. Their forward-thinking approach to piloting and deploying RTLS technologies throughout their three hospitals has already yielded significant benefits in terms of improved clinical operations and decreased costs.

"*We're very pleased that Mid Yorkshire Trust so quickly moved from its successful pilot program to deployment of our Asset Management and Environmental Monitoring solutions across its sites,*" said Greg Borecki, VP sales, international and strategic alliances, STANLEY Healthcare.

"*It's rewarding to help industry leaders discover new ways to overcome the practical, day-to-day challenges of healthcare delivery.*"

ABOUT STANLEY HEALTHCARE
STANLEY Healthcare provides over 5,000 acute care hospitals and 12,000 long-term care organisations with enterprise solutions that transform safety, security and operational efficiency. The STANLEY Healthcare solution set enables customers to achieve organisational excellence and superior care in five critical areas: Patient Safety, Security & Protection, Environmental Monitoring, Clinical Operations & Workflow and Supply Chain & Asset Management. These solutions are complemented by consulting, training, implementation and integration services. STANLEY Healthcare is proud to be part of Stanley Black & Decker, Inc.

For more information, visit **www.stanleyhealthcare.com**.

Changing the Culture
# towards Medication Errors in the NHS

MDET talks with **Dipak Duggal**, MRPharms, MBA, Director Global Solutions & Marketing at BD (Becton, Dickinson and Company) Dispensing Hospital International about the increasing interest in medication errors in the NHS

NAMDET: Why are medication errors now being talked about more within the NHS?

DD: Health and Social Care Secretary, Jeremy Hunt, recently declared that new patient safety measures will be put in place to reduce the current rate of medication errors in the NHS. He was moved to act by various pieces of evidence that point to the high clinical and economic costs of medication errors.

For example, a recent report from the Universities of York, Manchester and Sheffield highlighted the high incidence of medication errors in the NHS.

The researchers reported an estimated **712 deaths from avoidable adverse drug reactions** (ADRs) in the NHS each year but noted that ADRs could contribute to up to **22,303 deaths a year.**
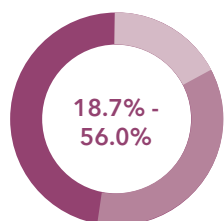
18.7% - 56.0%

Studies show that **18.7% - 56.0% of all adverse events among hospitalised patients result from preventable medication errors.**

As well as impacting on patient safety, medication errors are costly to the NHS - **estimated to account for around £1.6 billion per year.**

NAMDET: Are there particular stages of the medication process in which errors are more likely to occur?

DD: Typically, medication errors occur at the prescription, dispensing and administration stages, although most medication errors occur during the prescription and administration phase.

60%
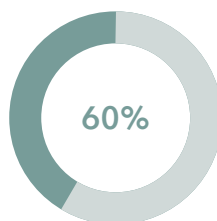
Around **60% of hospitalised patients receive medications via the intravenous (IV) route,** so it is unsurprising that studies show that medication errors are particularly likely to be linked to IV infusion administration. In fact, IV errors represent more than half of the adverse events due to medication among hospitalised patients, showing that reducing them must be a priority focus for Trusts.
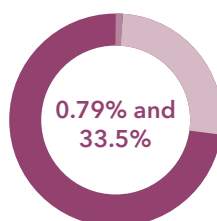
0.79% and 33.5%

Dispensing errors may be under-reported but are highly varied; **prospective observational studies report them as between 0.79% and 33.5%.**

43%
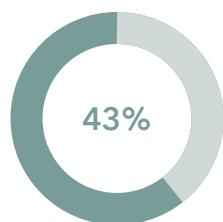
Preparation errors have been described in a recent UK study; **incorrect product labelling was identified in 43% of doses, the incorrect diluent was selected in 1% of cases,** and at least one deviation from correct aseptic technique was observed among 100 cases.

1%

Prescription errors also occur, but will be reduced with the introduction of e-prescribing solutions, that are increasingly widespread in NHS hospitals.

NAMDET: How is automation helping to reduce medication errors?

DD: Automation within the medication process is important in the prescription, dispensing, preparation and the administration stage.

At the prescription stage, automated and standardised solutions – such as e-prescription systems – can be applied to help reduce prescription errors especially when they are caused by inaccuracies resulting from staff shortages and lack of time.

At the dispensing stage, automated workflow solutions can support staff locate the right drug, in the right dose, in the right concentration, delivered at the right time.

At the preparation phase, an integrated, auditable gravimetric solution from a medication workflow perspective helps avoid medication errors at all stages of the process and provides valuable data.

At the administration stage, increased automation has been shown to help reduce dose errors, since a closed-loop system used with an updated and extensive drug library, infusion analytics, enterprise management software and patient-centred clinical services can enhance patient safety, clinical efficiency and reduce costs.

## NAMDET: How can we change the culture towards patient safety?

DD: The implementation of a holistic patient safety culture is linked closely with automation. This can help hospitals to achieve 'The Five Rights of Medication Administration' - as set out by the Institute of Healthcare Improvement – which advocates that, to reduce medication errors and harm: the right drug administered to the right patient, at the right dose, via the right route and at the right time.

The main aim is to instil an enhanced culture of patient safety in the NHS from the top down. Whilst technology needs to play an increasing role, a change process is needed to encourage medication error reporting and allow the NHS to learn from errors.

A crucial part of this for patient safety is how technology is implemented and used in hospitals. Hospital teams must be educated about managing risk, reporting events and learning from them.

Any technology introduced must be a flexible system of information-sharing that flows between platforms and clinical information systems, with the user at its heart. Systems must
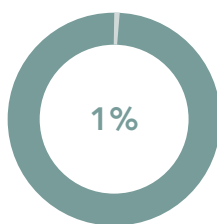
be customisable for the individual hospital unit to allow for complex compounding and particular dispensing workflows. Units that have successfully introduced automation within the pharmacy have shown that there can be more focus on clinical aspects of work and less on the processes of dispensing medicines. This enhances patient safety.

Another critical element in changing the patient safety culture – also linked to automation - is the increased use of unique identifier barcodes to ensure that the right drug reaches the right patient. The imminent introduction of the Falsified Medicines Directive, being mandated in February 2019, that all starting materials have GS1 standard barcoding, emphasise the importance of enhancing safety and increasing technology in the medication workflow process.

Together, these advances will further emphasise the safety message and change the culture towards medication errors.

NAMDET: What is your main message for our readers?

DD: It's clear that engaging in innovation isn't just about purchasing new technology, but also about understanding the potential benefits this technology can bring when combined with training. Staff must be engaged to ensure that patient safety is promoted in all processes and by everyone.

The combination of adopting technological advances and senior buy-in to the impact of medication errors is a key feature of the examples of success that BD has seen - where hospitals and Trusts tackle medication errors together, identifying the gaps and shortfalls and addressing them.

Medication workflow solutions alone will not enhance patient safety; they must be embraced and then bound together by an NHS commitment to encourage more transparent medication management that is efficient and empowering, and ultimately leads to improved patient safety. This is everyone's goal in the spirit of: Do no harm.

Further reading
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National Standards

The need for a national standard for Hospital/Theatre Access for external contractors/ company representatives who require professional face-to-face interaction with healthcare professionals and patients.

In March the Professional Standards Authority for Health and Social Care approved the addition of a credentialing register for the Life Science Industry to the existing Accredited Register run by the Academy for Healthcare Science.

This register is the first of its kind and sets national standards for healthcare professionals working in the life sciences industry, providing reassurance to the NHS. Under the Accredited Registers programme, practitioners on the register will be able to display the Accredited Register quality mark, a sign that they belong to a register which meets the Professional Standards Authority's robust standards. Diane Irvine, CEO of HC Skills International, discusses why national standards in this area are very much needed.

As we know, there are significant risks and liabilities in clinical areas.

For Hospitals to effectively Risk Manage this situation the medical device/pharmaceutical company representative should show evidence of competence to be admitted to and to work within a clinical environment.

Currently all liability is carried by the hospital because:

• **no contractual link** exists between the individual representative and the hospital.

• **no contractual link** exists between the company (supplier) and the hospital

This is further complicated as medical device/pharma company representatives are external service providers who are admitted to hospital clinical areas without having first signed a contract. It is also interesting to note that whilst the Product carries a master indemnity, no such indemnifying agreement exists for medical device company representative supporting that product in a clinical environment.

Without qualifications, patient safety could be compromised, and unsatisfactory surgical outcomes that are linked to the presence of unqualified individuals in clinical areas could be shown to be the responsibility of hospital management who may have failed to act to address the presence of an unquantifiable legal risk.

The primary aim is to safeguard patients and staff, by risk managing access to patient facing areas, improving infection control, ensuring that the right people have the right qualification and standard of training to be in a hospital setting.

Most hospitals will have a Practice Development or Learning and Education Framework that supports competency-based learning programmes within their structure for employees. However, this doesn't extend to external contractors or company representatives necessary to provide support to medical and nursing staff in their delivery of quality care to patients.

Until now, there have been inadequate guidelines and no regulations setting out the exact standards of professional practice required of non-clinical individuals that would ensure they comply with accepted or implied standards.

But that doesn't mean there aren't good legal and clinical reasons to do so.

This paper gives a brief backdrop to the topic and goes on to look at some of the legal aspects that hospitals may want to review when considering whether a national occupational standard is right for them. The need to safeguard our patients from harm is paramount when in our care. This will also address other factors that drive the need to have a Gold standard approach to the delivery of appropriate training.

Legal and ethical obligations

The mention of negligence claims immediately thrusts legal considerations into the spotlight. What are the main issues that hospitals need to be aware of in this respect? A useful starting point is this from the NHS Code of Practice 2003:

"…anyone who is invited into Hospitals or areas of clinical care in an advisory capacity is bound by the same legal and ethical obligations as those employed within the NHS"

Department of Health, Confidentiality: NHS Code of Practice, July 2003.

In other words, commercial visitors - for example medical device experts - visiting clinicians or administrative teams on hospital premises effectively become members of staff in the eyes of the law. As a result, the hospital is potentially liable for their behaviour and actions, and the impact of these, on the safety of staff and patients.

The legal view that commercial visitors are members of staff while on site also places a responsibility on the hospital as an 'employer' to ensure their security and safety.

The Management of Health and Safety at Work regulations (1999) therefore apply. They state that every employer shall make a suitable and sufficient assessment of:

• The risk to health and safety of persons not in his employment, arising out of or in connection with the conduct by him or his undertakings.

• The risks to the health and safety of his employees to which they are exposed while at work.

Not only does the law require that employers carry out risk management assessments, but they must also provide clear written evidence that they have done so.

In the eyes of the law, therefore, hospitals have a duty of care for commercial visitors and are vicariously liable for their actions while these visitors are on site. Vicarious liability refers to a situation where someone is held responsible for the actions or omissions of another person. In this context the hospital as 'employer' is liable for the acts or omissions of commercial visitors as 'employees', provided it can be shown that these acts or omissions took place in the course of their employment (i.e. visit to the hospital). In view of this, it is vital that hospital managers ask themselves:

• **Do I know, at all times, what visitors we have on the premises?**

• **What is the extent of their activities?**

Independent report published in February 2015, Jimmy Savile NHS investigations: lessons learned set out recommendations as below:

"Our recommendations for NHS hospital trusts are also addressed to Monitor and the Trust Development Authority under their duties to regulate NHS hospital trusts. Most of them are also addressed to:

• The Care Quality Commission under its duties and powers to regulate and assure the quality and safety of hospital services;

and

• NHS England under its duties and powers to promote and improve the safeguarding of children and adults.

All NHS hospital trusts should develop a policy for agreeing to and managing visits by celebrities, VIPs and other official visitors. The policy should apply to all such visits without exception."

Assessing and managing risk

Given that hospitals have a legal obligation to assess risk and prevent commercial visitors from harming others or themselves, are the risks really that great? Potentially, yes.

Representatives often have very close contact with patients, and work in sensitive hospital areas where following decontamination protocols or having access to sensitive data information can significantly impact patient outcomes.

In the UK it is common practice for representatives from medical device firms to attend and verbally assist, in a technical capacity, procedures involving their products. For example, medical device reps may be present in theatre to assist with a surgeon's use of a particular instrument, implant or other product. The level of expertise offered can be such that procedures may be cancelled if the appropriate product specialist is not present.

Prohibited, of course, is 'medical involvement' i.e. an attending representative making a medical judgment or participating in the procedure – in such instances both the hospital and the medical device representative (and the company they represent) could be held liable should there be an adverse incident as a result of those actions.

Risk is not restricted to the operating theatre. Any commercial visitor on site has the potential to directly influence patient health outcomes through their actions, omissions or health status. That is why training is so important.

This is highlighted by industry bodies such as BAREMA (the Association for Anaesthetic and Respiratory Device Suppliers) in their support and promotion of best practice training for industry representatives. Infection control, decontamination, consent, confidentiality, risk management and operating room procedures/protocols are just some of the areas that representatives should have training on before entering hospital premises in a consultative capacity.

> But what if representatives visiting a hospital area don't have the necessary training or if a particular representative known to a hospital has changed companies or product specialism?

Expecting them to have the necessary training and assuming that they do, is very different to demonstrating verifiable competence – particularly in terms of liability and negligence. It is also important not to forget the training obligations of those medical professionals that healthcare industry representatives advise:

"A healthcare organisation could be held responsible, under both health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage, as a result of inappropriate purchase or prescription of a device."
(Managing Medical Devices Bulletin April 2014)

> Risk assessment and management processes therefore need to include analysis and verification that company representatives have received the right level of training.

In this respect, it could be argued that an audit trail showing that a representative has visited a site and delivered training to a member of hospital staff is just as important as checking the representatives' credentials.

Vicarious liability and medical negligence

In admitting a patient, hospitals immediately take on a 'duty of care' for that individual. Medical negligence claims are valid when both of these parameters are established:

• A breach in that duty of care is established
AND
• The breach is proven to have caused harm to the patient

So, what has this to do with policy compliance and national standards? Consider the following scenario.

A patient is admitted to surgery for a hip implant that is new to the market. Though he has received training, it is the first time that the surgeon has used this implant, and so a product specialist from the medical device company is present for consultation during the procedure. The surgery goes well but the patient develops an infection during the post-operative recovery phase.

On investigation it is found that the representative did not follow theatre protocols for decontamination and hand hygiene and is the likely source of infection. The infection occurred during surgery and would have been avoided had correct protocols been followed.

Applying the first of the above parameters, by not following protocols, a breach in duty of care can be established. The second parameter is established by the fact that the infection developed by the patient during the post-operative recovery phase has harmed the patient.

As we have previously established, while on hospital property and working in a consultative capacity the representative is the responsibility of the hospital. Because the hospital failed to check that the representative - effectively an employee here - had the appropriate training in theatre protocols, a patient was harmed while in the hospital's care. It was a foreseeable risk that could have been avoided. Therefore, the hospital is deemed liable.

This is just one scenario, but it demonstrates both the legal implications of the privileged access to patients and property that representatives have (and need) in doing their job and that liability is not always cut and dried.

Often, only material contribution has to be proven i.e. the contribution to blame has to be 'more than minimal'. It's possible, for example, that something as apparently harmless as a reduction in the hospital's cleaning budget could contribute to a patient contracting a harmful bug that might have serious health implications. As long as contribution to blame is more than minimal, there is a potential claim against the hospital. With that in mind, it is easy to see how the hospital's failure to suitably enforce patient safety policies and hospital access procedures could come under fire.

Patient safety - an NHS priority

2014 saw Health Secretary Jeremy Hunt launch the 'Sign up to Safety' campaign to safeguard patients and reduce preventable harm, with the aim of saving 6,000 lives over the next three years. Tackling preventable healthcare associated infections such as MRSA is a key NHS priority. Therefore, ensuring commercial visitors have received training on infection control/decontamination policies and procedures are vital.

Indeed, according to the National Audit Office, compliance with hospital policies is among the top three most important measures for combating hospital infections.

NHS budgets

Consider that the annual amount set aside for NHS negligence claims is now standing at a predicted figure in excess of £65 billion (FEB 2018) – alarmingly, an amount exceeding the entire non-pay budget of the NHS.

Another important cost area is NHS supplies, covering anything from catering items to forceps and knee implants. A report by consultants Ernst and Young at the end of 2012 revealed that pricing disparity in the supply of products is costing the NHS £500m a year – a massive drain on the NHS budget. The causes of this are many and varied, and include the sidestepping of central procurement by representatives and the purchase of unsanctioned products without sign off from procurement.

The sums make a compelling case for reducing risk and avoidable expenditure – two areas that policy compliance and national standards help address.

The situation is similar in the private healthcare sector, where managers face increasing pressure to keep costs down and clinical standards high.

Managing the risk through national standards

Managing risk to avoid the liability issues outlined in this paper cannot be accomplished in one single step and policy enforcement is not the sole answer. But it can significantly help by:

• assisting the hospital to demonstrably execute on its duty of care obligations

• ensuring that commercial visitors meet the hospital's requirements for access to patient sensitive or restricted areas

• ensuring that a national standard for hospital/theatre access is the "gold standard"

• ensuring that hospital management know who is on site at any time, and why

• providing an audit trail of activity

In effect, it is a vital safety umbrella that can not only reduce risk to patients but also reduce risk for the hospital.

Negligence and liability are sometimes overused words in healthcare settings, and can lose their meaning - until a theoretical case becomes reality. Effective risk management is essential to protect patients and healthcare providers - therefore policy compliance and national standards are important considerations that everyone should address.

Have your say
on the future of NHS patient safety investigation

By Lauren Mosley, Head of Patient Safety Implementation, NHS Improvement and Donna Forsyth, Head of Patient Safety Investigation, NHS Improvement
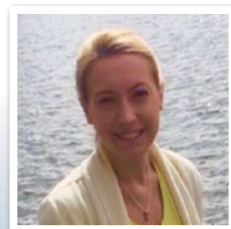
Lauren Mosley
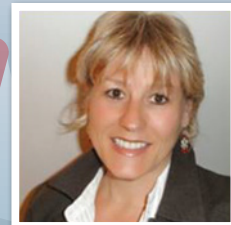
Donna Forsyth

The NHS conducts patient safety investigations after things go wrong in patient care so learning can occur to inform changes that will help prevent similar incidents happening again. The current Serious Incident Framework published in 2015 sets expectations for when and how the NHS should conduct a safety investigation.

However, compelling evidence from patients, families, carers and staff has revealed weaknesses in the way NHS organisations investigate, communicate and learn when things go wrong. This evidence forms the cornerstone of many recent national reports and reviews on the issue including those published by the Public Administration Select Committee (March 2015), the government's response to that report (July 2015), the Parliamentary and Health Service Ombudsman's report (December 2015) and the Care Quality Commission's (CQC) Learning, candour and accountability (December 2016).

These reports and the evidence from patients, families, carers and staff have identified shortcomings in adherence to the guidance in the Serious Incident Framework, and problems with existing investigation practice across the NHS in England.

While the Healthcare Safety Investigation Branch (HSIB), launched in April 2017, will undertake a number of independent exemplar investigations (exploring issues that exist across the whole system), HSIB cannot lead all investigations that are required across the NHS. This means NHS organisations continue to play a crucial role in identifying why incidents have occurred and what can be done to reduce the risk of them happening again.

Therefore, the Serious Incident Framework continues to be a key document in setting expectations around investigations.

Our programme of engagement
To ensure investigations conducted by NHS organisations maximise opportunities for learning and improvement, the NHS Improvement national patient safety team is leading a 12 week engagement programme, that remains open until 12 June 2018, to gather views on how and when the NHS should investigate Serious Incidents. Responses will be used to shape a new Serious Incident Framework document likely to be published by the end of the year.

Key issues being explored
While the Serious Incident Framework sets clear expectations on provider organisations, we now know that providers are not all able to reliably and routinely meet those expectations.

Similarly, while the Serious Incident Framework makes organisations accountable to their commissioners for carrying out good quality investigations, and CQC considers the process of investigation in its inspections, these accountability systems are not ensuring good quality investigations take place.

Through our work and the work of others (particularly the CQC), we have identified several key areas of concern in relation to current NHS investigation practices that we are looking to explore, discuss and gather feedback on throughout the engagement period.

These key issues are summarised below:
- Failure to ensure proper patient, family and carer support and engagement in investigation processes
- Lack of staff support and engagement during investigations
- NHS organisations are completing high volumes of investigations and the quality of investigations is generally low
- Misaligned oversight and assurance processes
- Staff in provider organisations report having insufficient time, expertise and resources to conduct good quality investigation
- A focus on meeting the current 60 day deadline to compete a Serious Incident investigation is often prioritised over the delivery of good quality investigations in a timely manner
- Lack of uptake of the standard investigation approach and investigation report templates
- Lack of clarity around patient safety investigation principles and purpose
- The Serious Incident investigation process, language and terminology is perceived as punitive and inhibits improvement

We want to hear what you think
We want as many people as possible, from a range of different roles, levels of experience and backgrounds, to share their views with us through our online questionnaire. To make the engagement period as interactive as possible, we are also planning a range of other activities including face-to-face events, videos, twitter chats etc.

The questionnaire and further details are available on our website, along with the discussion document that provides context to the questions, and a 30 minute video of a recorded webex presentation https://improvement.nhs.uk/resources/future-of-patient-safety-investigation/.

The questionnaire remains open until 12 June 2018. This is your chance to help us shape the future of NHS patient safety investigation.

TEAMING UP

Dawn Stott
Chief Executive
The Association for
Perioperative Practice (AfPP)

It was announced on the BBC at the start of 2018 that 33,000 nurses are leaving the profession, 3,000 more than joined. How can this be? How can people feel so under pressure due to staff shortages etc., that they have to leave their chosen work habitat to ensure they have a good work life balance?

The Royal College of Nursing (RCN) state that one in nine nursing positions are vacant at the moment. This adds extra pressure to the already understaffed teams left working in NHS hospitals and community. People who join the profession should not be brought to tears because of the pressures. When we speak to our nursing membership they nearly always say that they joined the profession to 'make a difference', they wanted to 'ensure patients receive the right level of care in a safe and supportive environment'. AfPP knows that we are losing knowledge and skills from the perioperative environment due to the downward spiral of leavers. We see teams experiencing sickness, stress and depression due to the extra pressures placed on them, which ultimately impacts on patient safety and continuity of care. Our nurses are even moving overseas for a better quality of life. How can that be right?

The BBC stated that around 7,000 nurses who left the profession were over 55 years of age; 9,500 were in the age bracket 40 - 54 and 17,000 were under 40 years. How are we going to bridge that knowledge gap? There has been a 20% increase in leavers since 2012/13 resulting in more leavers than joiners. In the last three years more than 10% of the nursing workforce have left the NHS in each of the years. In reality this is enough manpower to staff more than twenty average sized trusts.

Based on the BBC statistics even the EU nurses who come across to England for a better career and to bolster our nursing numbers are leaving! I think we all know why.

Jane Cummings CNO for England, told BBC news that they were aware of the issues and were working hard to stem the flow; they were working with the RCN to introduce Nurse Ambassadors to support colleagues and spread the word about nursing as a profession. Is this too little too late? We should be looking after these valuable and dedicated professionals, introducing new titles to support the healthcare teams, but whilst this may appear on paper a great way of supporting an overwhelmed workforce, the reality is that it probably isn't the answer. I trained to be a nurse in the 1970's when a girl's career advice was pretty much, you can be a teacher, secretary or nurse. My Grandfather insisted I would make a great nurse, sadly he was wrong and after a year I left the course for different reasons to those faced by current professionals, I couldn't stand the sight of blood and other bodily fluids! My Father suggested I should learn to type as I would always have a job - he fortunately was right. I have worked in and around healthcare for nearly 30 years and am

passionate about care for both the patients and those people delivering the care and often feel sad that as an organisation we hear so much negativity from our core membership around workload pressures and lack of support from senior management.

Things are not going to change unless the Minister for Health and Social Care understands the real problems in hospitals, and rather than cancelling everything due to winter pressures, leaving everyone in 'catch up mode', getting to the heart of the problem and stemming the flow rather than just sticking their finger in the hole!

AfPP has around 7,000 members throughout the UK and overseas. Our vision is to Lead Perioperative Excellence. The aims of the Association include patient safety in operating theatres, the promotion of high standards of perioperative care, the exchange of professional information between members and co-operation with other professional bodies. The board of AfPP comprises elected trustees and co-opted trustees, who are based throughout the UK and work in a voluntary capacity in addition to their full-time healthcare roles. We are no longer just a nursing association, we represent all perioperative practitioners, registered or unregistered, at the start of their career or those with many years of experience. We are here to help the perioperative fraternity be the best they can be. We produce a wide range of publications which offer guidelines, advice or recommendations for best practice in operating departments.

At AfPP we believe that team training is essential; if you work together you should learn together as this gives a team purpose, everyone has a clear understanding of expectations and believe strongly in what they have been brought together to achieve. Through team focus their purpose is strongly at the front of their minds, underpinning their actions and decisions. The purpose isn't just about the mission and goals, but also about aligning the team and defining how they work together. They must have a belief that they are capable of achieving their goals together. We have built a programme of whole team training that supports trusts and the independent sector to build strong and adaptable theatre teams that are confident to challenge and share their failures and successes in equal measure.

Unfortunately, in many healthcare organisations the senior teams are too far removed from the 'shop floor' to understand the pressures being placed on teams and do not understand the values required to develop an interconnected team that has real support for each other; they do not stick their heads above the parapet to understand the real issues that practitioners are facing. Maybe if they did not so many experienced, passionate and talented people would be leaving the profession.

Behavioural change for trainers:
understanding perceptions to optimise device training programmes

Tom Kenny[1], Chloe Tuck[1], Eva Raebel[1]

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Professionals working in the dynamic world of healthcare are routinely faced with diverse challenges. Continuing, high-quality training, delivered in a resource-efficient way, is paramount to ensure staff are equipped with the most up-to-date skills resources to enable them to act effectively and engage with devices in the optimal way. In many situations, providing effective training in using devices requires changing complex behaviours during training. This can include the way staff approach their work, new set-up of safeguards, procedures to follow when using new equipment, or how to interact with a device under time pressure. However, evoking this change in behaviour is not a simple task: it requires for trainers to go beyond the provision of information, and to address the perceptual and practical drivers underlying uptake of, and persistence with, a behaviour.

By using a behavioural science approach to training in the use of medical devices, and carefully crafting the training programme to consider the complex factors underlying engagement with behaviours, we can maximise the capacity for behaviour change and ensure devices are used to their full potential, hence deliver the benefits that are intended for the patient. Below we outline some principles in designing training within a healthcare setting to achieve best outcomes.

Perceptions and practicalities -
understanding the behavioural barriers

Effective training forms a bridge to support your students with the transition from current behaviours to the new behaviours you are aiming them to achieve, but to accomplish an effective and lasting switch, you must first understand the barriers and drivers they face to adopt this change. These barriers can often be multifactorial and interdependent therefore, it is helpful to categorise them using well-tested psychological models and frameworks, so they can be better understood and appropriately addressed during training. The Perceptions and Practicalities Approach™ (PAPA) is a conceptual framework that can be applied to inform the trainer of the obstacles that could be encountered when trying to support staff with a behavioural change, so appropriate psychological techniques can be incorporated into the development of the training programme. PAPA™ categorises barriers to a behaviour as either practical, due to capacity and resource, and perceptual, due to underlying beliefs. Examples of several practical and perceptual barriers to the optimal behaviour when setting-up and using an infusion device (adapted from findings of Iacovides et al., 2016)[1] are shown in Box 1.

Practical barriers	Perceptual barriers
Having to change measurement units and standards used when setting up a device which results in extraneous calculations	Concerns about safety
Lack of clarity with interface symbols and options	Trust in routine and previous experience
Lack of support to understand all device settings	Trust in practice of others
Limitations to device configuration for clinical area	Concerns around accountability for errors
Lack of time	Concerns about trusting automation and programming reliability
Ward layout	Lack perception of importance for patient safety
Limited device functionality and alignment with real-world use	Assumptions device will notify if errors occur
Lack of skill using a device and calculating settings required	Do not recognise a procedure as import and distinct
Demands from competing heavy workload	Conceptualisation of how a process works when using a device
	Belief patient will complain
	Lack belief of necessity of alarm system
	Concerns about noise

Box 1. Examples of practical and perceptual barriers that could affect behaviours around setting-up an infusion device. Taken from observational insights from Iacovides et al., 2016[1]. (To note, these are illustrative examples, not intended to exhaustively cover all practical and perceptual factors.)

Practical barriers are unintentional, for example, when a lack of skills and knowledge hinders correct use of a device. For example, when setting up home healthcare devices, lack of standardisation across devices or insufficient instructions can pose a barrier to correct behaviours.[2] Incorrect behaviours that have become routine can also be considered as practical barriers. When routines become hard-wired, they are no longer easy to change and transforming them requires a large amount of cognitive capacity and resource on the part of the individual to change their behaviour.

Practical barriers are usually addressed by traditional training programmes and behavioural interventions, perceptual barriers are often not. Overcoming perceptual barriers is crucial to changing behavioural patterns long-term. Assessing interventions to change health behaviours taken from the Cochrane Database[3] have demonstrated addressing both perceptual and practical barriers, as well as a personalised approach, are strong predictors of the intervention success.[4]

Training programmes that incorporate behaviour change to allow for perceptual and practical barriers will be most successful, as these are often interlinked, and the overall behavioural outcome can frequently be a consequence of a multifactorial response to both. Given that perceptual barriers to behaviour are most often overlooked, we will focus on how these can be targeted within training using behaviour models.
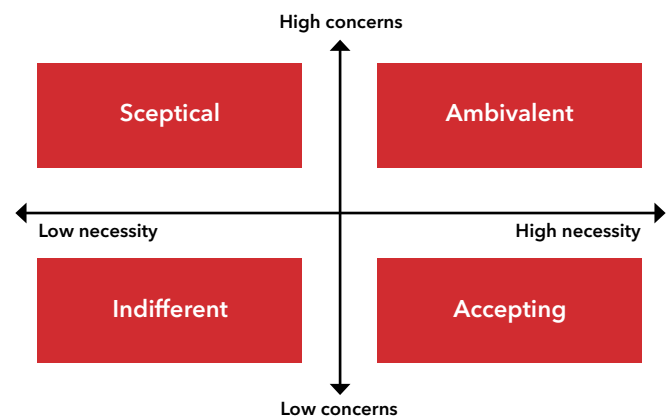
Perceptions underpinning intentional behaviours

How can we map perceptions to behaviours?

There are several models that have been used to map how perceptions influence behaviours in other health-related settings, such as medication adherence, that can be applied to understand the impact of perceptions on behaviours achieved through training. One key model is the Necessity-Concerns FrameworkTM.[5] First used to model non-adherence, this framework conceptualises a behaviour as a trade-off between one's beliefs in the necessity for undertaking a behaviour, and the concerns about doing it.

Using this approach, we can create a map of attitudes (Figure 1.). Those who have high necessity beliefs regarding a particular behaviour, and low concerns about doing it are most likely to engage with the behavioural change.[6,7] Conversely, those with higher concerns, and lower necessity beliefs are less likely to engage in a given behaviour. Therefore, an effective training programme should aim at shifting participants into an accepting stage (Figure 1., bottom right quadrant).

Figure 1. Three-dimensional map of factors that contribute to the influence of perceptions on behaviours based on the Necessity Concerns Framework™. The horizontal axis represents level of necessity beliefs and the vertical axis represents concerns. When concerns are higher and when necessity beliefs are lower, a person is less likely to conduct a behaviour. This is most pronounced in the top left quadrant (sceptical). However, lower concerns and higher necessity beliefs, increase likelihood of engaging with a behaviour (bottom right – accepting). Adapted from Chapman et al., 2015.[8]

To move students into the accepting quadrant, and therefore change their behaviour, insights into their specific perceptions are required to ensure the training can reinforce and enhance their necessity beliefs for action and decrease the level of concerns they may have. We can apply the model to examples of perceptions found to influence the set-up of an infusion device in Box 1. Focusing on alarm settings in particular, to give an example. The perception of necessity for an alarm setting - its impact on patient safety - must be greater than concerns around noise pollution on the ward and need to spend time turning it off, for it to be perceived as required and thus engaged with.

It is also important to consider that not all participants will have the same perceptions and so their needs will not be the same. With this in mind, training should address the most significant key themes of beliefs commonly held by all students, but also have a capability to be tailored to each student's individual composition of these beliefs.[5]

Beliefs about the behaviour will also be influenced by many factors that vary over time. When information gets less of our attention it becomes less available and perceived as of less importance[9], for example, when a behaviour becomes routine. Therefore, reinforcement of necessity beliefs and addressing concerns is required to maintain a set of beliefs which align with conducting the intended behaviour in a sustainable manner.

Turning insights into impact

Apply perceptual understanding to change behaviours

Once insights into underlying perceptions that determine a behaviour are obtained, these findings can be applied to effectively change the behaviour in practice. In complex, real-world settings, such as in healthcare centres and hospitals, there are many logistical, as well as psychosocial factors to consider and ensure practical implementation is optimal. One effective model used to ensure behaviour change

initiatives are designed to consider these factors is the Three Components of Behavioural Change™ (3CBC) model.[10] This stipulates that the three key components to facilitate a successful change in behaviour are the content, channel, and context though which the behavioural intervention is delivered.

Content: This relates to the information that is going to be delivered through the training. This must be at the right level and tailored to the needs of the audience. Although it should provide new information and allow progress, it should not be too complex that the audience feels overwhelmed and become disengaged.

Channel: This refers to how the support will be delivered (e.g. face-to-face, paper form, internet). The optimal channel for engagement will vary depending on the needs of the audience. It should consider the environment they are working in, the time and resources available to them, who they engage with and who they would be receptive to receiving information from, as well as their ease with digital platforms.

Context: These are factors that contribute to form inconsistencies that bring training out of alignment with the audience's beliefs about their environment. This reduces the perception of value of the training and the impact and propensity for behavioural change the messages have. These can be social and cultural factors, as well as logistical features that impact on how messages are interpreted. For example, an iPad may work well for training within the context of a staff room, but not on a ward, where staff have limited internet access, competing demands, or are conscious that patients may watch them. An effective written training guide may be well supplemented with a video, or infographics, especially where language-fluency is low.

How training topics are named, as well as their accreditations, can also impact how they are perceived and engaged with. Involvement of the end users is important for contextual considerations. Gaining feedback and insights on the device training programme development at a nascent stage will allow key contextual factors to be identified. This will allow the training to be tailored to the needs of the students and most effectively change behaviours.

By considering the three factors outlined in the 3CBC™ approach together, you can ensure the training includes all the key elements for effective behaviour change.

Behavioural Science techniques communicate a perceptual change

Lastly, once you have deciphered the most effective delivery mechanism for your training to change the behaviour, the exact way to communicate the specific messages that will change the behaviour can be determined.

Communicating messages to change perceptions that are deeply ingrained, to students who may not always be extrinsically aware, requires more than information provision alone. Information will be essential to change the behaviour, but when displayed incorrectly will be counter-productive. Communication for behaviour change requires the application of psychological techniques. There are many psychological techniques that can make a marked influence in how information is assimilated. This will impact to what extent the information is considered, understood, and how likely it is to change an underlying perception and therefore lead to behavioural change.

An example is the Primacy/Recency Effect. In any learning episode, we are most likely to remember the start, followed by the end, and we remember the content in the middle the least. Therefore, it is important to deliver the most important messages for the audience at the start and end of the training session.[11]

To further enhance the effectiveness of your communication in eliciting the behavioural change you require, you can incorporate repetition, known as the Mere-exposure effect. Repetition increases perceptual fluency. As concepts become more familiar, they are seen as more preferable so we build a more positive perception of them.[12,13]How information is framed also impacts our behaviours. Framing information to highlight a gain over a loss increases positive sentiment, increasing likelihood of inducing a behaviour.[14]

Information is easiest to assimilate when structured into interlinking topics that the audience can progress through, mentally connecting each piece of information. Conversely, when information is too copious, not easily ordered, or is delivered in a complex language, it requires increased cognitive effort to assimilate and its impact is often lower. When digesting information people try to avoid large amounts of cognitive effort. Developing content which provides cognitive ease increases the likelihood of the intended change in behaviour.

Summary
Training to change behaviours, such as how healthcare staff interact with medical devices to optimise treatment outcomes, efficiency and safety requires an in-depth understanding of the many complex factors influencing these behaviours. This includes the practical and perceptual drivers that determine behaviours, which are often complex and multifactorial. Behaviour science offers effective evidence-based approaches to understand the behaviours acquired through training and apply such insights systematically to effectively change behaviours that will maximise healthcare staff outputs and, ultimately, benefit patients.

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Did you remember...?

Last issue we held a competition where NAMDET Chairman Paul Lee challenged us to recognise some medical devices of old. The winners were: *"The Old Crocs!"* also known as the Clinical Engineering Team QA Hospital, Portsmouth.

Congratulations to all who entered as the top three were very close, but Portsmouth just pipped it. A £50 online store voucher is now on its way to the South coast.

But for everybody else who pondered over the photos and had the name on the 'tip of their tongue', to end your frustration, here are the answers:

Photo number	Description	Manufacturer	Model
1	Infusion Pump	B Braun	DROPMAT
2	portable Oxygen Cylinder	BOC	CD (size)
3	Syringe Driver	Graseby Medical	MS26
4	Syringe Driver	Graseby Dynamics	MS16
5	Syringe Pump	Graseby Medical	3100
6	Defibrillator	Hewlett Packard	43120A
7	Vital signs monitor	Critikon	845XT adult/paediatric
8	ECT (electro convulsive therapy)	Ectron Ltd.	DuoPulse
9	Respiration Monitor	Graseby Medical	MR10
10a	Syringe Pump	Vickers	IP4
10b	Syringe Pump	Vickers	IP3
11	External pulse generator	Devices Ltd. (APC)	E4162
12	DC Defibrillator	S&W (Vickers)	DCX 822
13	ECG Monitor	Hewlett Packard	7830A

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