The Official Journal of the National Association of Medical Device Educators & Trainers

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MDET

The Journal of Medical Device Education & Training

Exclusive Report from NAMDET Conference

Competition: *Medical Device History*

Voices: *NHS Improvement AfPP*

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References
1. Valentin A, *et al. BMJ* 2009; **338:** b814.
2. Pepper GA. *Am J Health Syst Pharm* 1995; **52:** 390-5.

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Hi MDET Readers.

I want to start this editorial with a thank you. MDET has now been circulated both electronically and in hard print for twelve months and we have received many positive comments on our first four editions. So a particularly big 'thank you' to all of the contributors, advertisers, and to BD for their continued support.

In this publication, our fifth, you will read about the NAMDET annual conference which took place in November. This conference was the most successful event that we have undertaken and was again in the Birmingham venue that we have used before. The full conference speakers and what they contributed forms the bulk of this issue, so I will let you read for yourself.

The annual conference was closely followed by the Patient First event in late November. NAMDET were invited to attend and we were given our own 'theatre area' and exhibition stand to promote our work. We were also supported by the pharmacy section of NHS England which also gave updates to delegates. This event gave NAMDET the opportunity to speak to many delegates that we would not have access to during our normal activities. The theatre area was in the body of the exhibition hall and allowed many people to stand around the periphery, as well as sit and listen to our range of speakers. There were 60 seats but I counted over 100 people standing and blocking the aisles for many of our speakers. The talk on infusion pumps, given by our Chair Paul Lee, and the MDDL update by Tom Clutton-Brock were particularly well attended. Both talks were followed by very interesting and insightful questions and answers. The next edition of MDET will contain reports on some of the many interested topics discussed over the two days.

2017 has been a busy year for NAMDET with planning for the above events and work on ongoing projects, and have taken many hours of NAMDETs working group time. But all should see fruition and rollout in 2018. 2018 will also see an event focused on Dose Error Reduction Software (DERS) taking place in partnership with invited manufacturers; watch the NAMDET website for more information. And mentioning the website, in 2018 you will see an update version. This will incorporate new member areas and, for the first time, NAMDET membership cards with a unique membership number. But I will save the full updates on this initiative for the next edition of MDET.

Mike Peel
NAMDET Editor

This fifth edition of MDET incorporates the usual highly informative commentaries from our colleagues in organisations such as NHS Improvement and AfPP. In addition I was particularly interested to read the article on John Byrne's early life in medical devices - as a squaddy! John has been a Director of NAMDET from its inception and is Finance Director at present.

Sadly, many of the original NAMDET Board of Directors are now either approaching retirement or are considering it. Many of you will know that Andy Flood retired from his long career at Sheffield and has decided that he wants to hand over the managing of NAMDET's conference to a younger organiser. Andy was also one of the original NAMDET Board and will be sorely missed after his many years of stalwart service to NAMDET. In June of 2017 I also retired from my role at the MHRA after almost 20 years. Many of you will be aware that family issues and poor health during 2017 saw me back away from active work on the NAMDET board and also kept me away from the Annual Conference. However, I have still worked as Editor on MDET and also on the MDDL development..

The 'old guard' may be retiring, but NAMDET will continue to go from strength to strength and so I am asking for volunteers to step forward to carry on the great work. Please get in touch if you are keen to get involved.

Happy Reading and good luck in 2018

A HUGE leap

IT WAS ANOTHER RECORD-BREAKING YEAR FOR THE NAMDET ANNUAL CONFERENCE, WITH MORE DELEGATES THAN EVER BEFORE GATHERING IN BIRMINGHAM. IN OPENING THE PROCEEDINGS, NAMDET CHAIR PAUL LEE REFLECTED ON THE ORGANISATION'S ACHIEVEMENTS OVER THE PRIOR 12 MONTHS AND SAW EVIDENCE OF ITS GROWING INFLUENCE.

Paul Lee was seconded to NHS Improvement for 7 months this year, and it will come as little surprise that he seized any opportunity to get NAMDET better known at the national body.

"He was very evangelical about NAMDET and all the stuff you do," Graeme Kirkpatrick, NHS Improvement's Head of Patient Safety (advice and guidance) told delegates at the 2017 NAMDET Annual Conference. *"And we certainly see NAMDET to be a key partner with the National Patient Safety Team going forward."*

When Paul took to the stage, he had all manner of other examples of the association's growing influence in 2017. Chief among them were invitations to lend expertise to national projects, including the creation of Medicines and Healthcare products Regulatory Agency guidance.

"We helped contribute to the MHRA document on human factors and medical devices," explained Paul. *"It's a huge document on human factors, from procurement of medical devices to safe use as well; a great piece of work, and we're trying to get the MHRA to come around the UK and share that with you."*

There had also been involvement in work on specific devices, he said. "NAMDET was invited this year to contribute towards a patient safety survey around the safe use of medical gasses and oxygen cylinders.

"NHS Improvement will be looking at the survey that our NAMDET family put together to gauge opinion, and maybe give out some national advice on the safe use of such medical devices. So NAMDET has contributed towards a huge piece of work that may help direct some patient safety advice."

He added that it wouldn't be the only such opportunity. *"I've been invited on behalf of you as members onto a national safety panel,"* reported Paul. *"That will be a panel that helps contribute to the development of patient safety alerts, so NAMDET gets to contribute towards that content as well."*

The main topic on the agenda for the conference also centred on developing something which bolsters safety: namely, medical device training competencies. Ginina Houghton, national clinical manager at CME Medical, neatly summarised the arguments for such an approach.

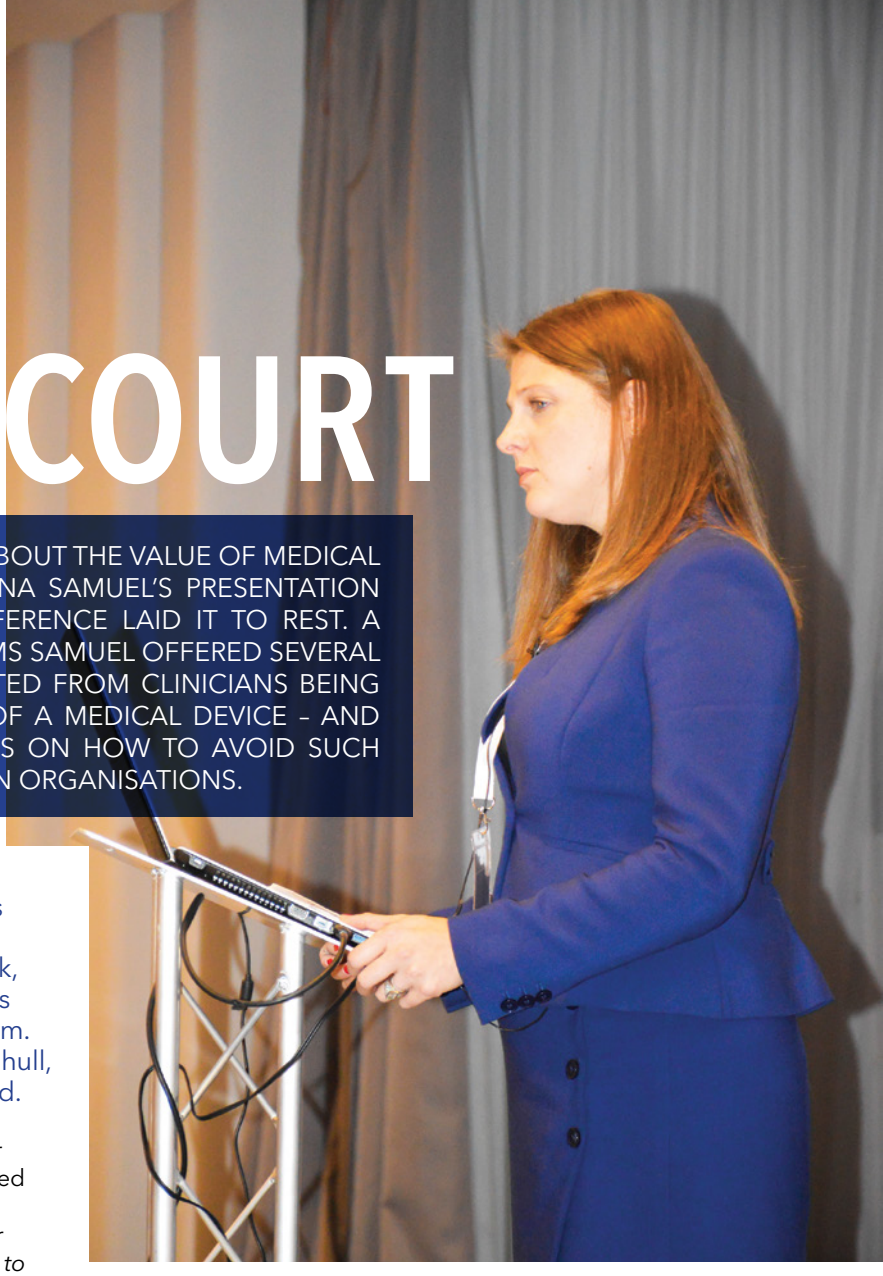
"Competencies and competency-based learning has a place where safety is an issue of concern," she suggested. *"It provides a framework that we're able to use to provide evidence for compliance, and more importantly allows users the ability to take ownership of their own learning through self-assessment and self-evaluation."*

Marie Law and Tammy Marsh, both from The Pennine Acute Hospitals NHS Trust and on the NAMDET management committee, told delegates of how they're hoping to create consistency in competency self-assessment across the NHS. Janet Clegg, meanwhile, explained how the trust had standardised peripheral cannulas to ensure all staff were experienced in the same device. And Ana Samuel, a specialist in clinical negligence and assistant coroner, gave examples of the tremendous harm which can result when there has not been adequate focus on ensuring competency in medical devices.

As befits an association of growing influence, there were also presentations from national figures on areas of broader interest. Michelle Dawson, a consultant anaesthetist at Derby Teaching Hospitals NHS Foundation Trust, detailed efforts to create the Life Science Industry Register. And Ellen Armistead, deputy director at the CQC, queried whether medical devices could be made a more central part of hospital inspections.

For Paul, 2017 represented a "huge leap" for NAMDET. In the following pages, MDET looks in detail at the many themes and projects covered at the conference which crowned the year.

HOLDING COURT



IF THERE HAD EVER BEEN ANY DOUBT ABOUT THE VALUE OF MEDICAL DEVICE EDUCATORS AND TRAINERS, ANA SAMUEL'S PRESENTATION TO THE 2017 NAMDET ANNUAL CONFERENCE LAID IT TO REST. A BARRISTER AND ASSISTANT CORONER, MS SAMUEL OFFERED SEVERAL EXAMPLES OF HARM THAT HAD RESULTED FROM CLINICIANS BEING INSUFFICIENTLY TRAINED IN THE USE OF A MEDICAL DEVICE – AND OFFERED SUGGESTIONS TO DELEGATES ON HOW TO AVOID SUCH SITUATIONS CROPPING UP IN THEIR OWN ORGANISATIONS.

Ana Samuel is very used to hearing about problems with medical devices. As a barrister specialising in clinical negligence, personal injury and inquest work, she frequently represents families and trusts in cases where some kind of device problem has caused harm. And as an Assistant Coroner in Birmingham and Solihull, she sadly often hears about deaths that have resulted.

Sometimes the issue is a failure with the device itself. Other times the problem will have been that the surgeon implanted it incorrectly. But, she told delegates at the 2017 NAMDET Annual Conference, the more common problem is whether there has been *"appropriate training or instructions on how to use a medical device".*

"And then there's issues about reviews and updates," she added. *"Have there been reviews of the training, have there been updates if there's been any changes in relation to the medical devices? And has there been auditing, in terms of making sure not only that all the parts of a device are present and are set up correctly, but also auditing in terms of the training."*

Coroners, Ms Samuel went out to explain, are under two primary duties – the first to investigate unnatural deaths, and the second to consider whether a report needs to be prepared to prevent future deaths.

"So the coroner is concerned not only with the death in front of them, that they're dealing with in respect of that inquest," she stressed, *"but also whether there is a risk of any other deaths arising as a result of any factors that are relevant to the specifics of that inquest."*

Ms Samuel could offer no shortage of examples in which coroners had highlighted concerns about medical device training. And she explained that such worries need not necessarily have caused a death for coroners to raise them.

Take the case of John William Rogers, who was found collapsed on the floor next to his hospital bed. He died from multiple organ failure caused by pneumonia and liver disease, but the inquest revealed clinicians' attempts at resuscitation were hampered by a lack of up-to-date training.

"Have there been reviews of the training, have there been updates if there's been any changes in relation to the medical devices? And has there been auditing, in terms of making sure not only that all the parts of a device are present and are set up correctly, but also auditing in terms of the training."

"Resuscitation was attempted by use of a defibrillator," explained Ms Samuel. *"The issue in this case was that the nurse set the defibrillator to two joules rather than the required 150, and that wasn't noted by the nursing staff until around 30 to 40 minutes after the resuscitation had commenced. The member of nursing staff who was operating the equipment on this occasion I think in the past had used it on an automatic setting, but on this occasion was using a manual setting for the first time."*

That wasn't the only issue. *"Her advanced life support qualification had expired at the time of this incident. So, understandably, the coroner was concerned about both of those issues, and sent a report to the hospital. It said the matters of concern were that the current systems were not sufficiently robust to ensure that staff were appropriately qualified to undertake the work required of them, and that their training and qualification requirements remain up to date."*

Sometimes such failings result from a lack of clarity over responsibilities, Ms Samuel suggested. She pointed to the case of Simon Harper, whose portable oxygen cylinder was not switched on during a transfer.

"As a result, this gentleman's heart stopped, and he was resuscitated but died two days later. The issue was that the nurse didn't turn the valve on to allow oxygen to flow. The concerns flagged up in this inquest were that only one training session had been provided by the external provider to a group of nurses.

"Thereafter there was reliance on peer-to-peer training with no records being made by the hospital as to who had received the peer-to-peer training, and no audits being done to ensure that training was effective, in that the nursing staff understood how to effectively operate the machinery."

Ms Samuel said she would like to say such a situation was an unusual one, but: *"Regrettably, it's not."* She recalled three years ago that she'd been involved in an inquest for an almost identical case.

"Again it was quite clear that there was a confusion in terms of who was responsible for providing training, but also who was responsible to receive that training, in that I think historically the porters had been responsible for turning on the portable oxygen devices. But, in this case there was no porter available and therefore the nurse stepped in and was involved in the transfer.

"I understand there also appeared to be an issue as to whose responsibility it was to train in this situation. Was it the company that provided the oxygen cylinder, was it the hospital in terms of the nurses, bearing in mind that she was the person that operated the cylinder, or was it perhaps pharmacy, bearing in mind that I understand these portable oxygen cylinders are classed as drugs and therefore would fall under the pharmacy."

> ***"Training, as I say, seems to be the key matter."***

Ms Samuel said that, in her opinion, it's preferable for several organisations to offer the same training rather than for insufficient learning to be offered by one. *"No coroner is ever going to criticise – and I don't believe that any patient is going to criticise – over-training, but clearly under-training gets you into hot water."*

As further evidence, she cited the 2013 death of three-day-old Billy Wilson. He died of brain damage due to oxygen insufficiency, after a newly-qualified midwife failed to realise an emergency caesarian section was required.

"The midwife failed to appreciate the readings from the CTG (cardiotocograph) printout, and therefore tried to continue to induce labour when the induction should have stopped and there should have been an emergency caesarean.

"This midwife hadn't received instructions or training on the midwifery course at university," added Ms Samuel. "When she took up her first appointment, she didn't complete the second part of the e-learning course. The evidence from an expert who gave evidence before the coroner was that unfortunately lack of training was commonplace in this sort of situation, and therefore concerns were raised."

Those concerns were shared broadly: the university was contacted to ensure all future students completed the relevant component of the course; the National Midwifery Council to ensure that prior to registration such competencies were satisfied; and the employer to ensure that suitable training was available for staff in post.

Yet despite all this, Ms Samuel said her research showed a similar incident had happened in a different hospital. And three weeks prior to her presentation to colleagues at the NAMDET Annual Conference, which took place in early November 2017, she'd represented a trust in a case where it became clear there had been inadequate training on suction devices.

"While not causative of this gentleman's death, there was an issue in that the suction machine when the nurses came to use it wasn't set up correctly, and then they had difficulties trying to set it up. It transpired that there was no training in place as to how set up the suction equipment, nor any training in place as to how to use.

"And perhaps more crucially in that case, there were no measures in place to ensure that there was regular inspection and/or maintenance of that piece of equipment to ensure that it was ready to be used in the event that it was necessary.

"So similar themes are coming out through all of these inquests," she said. *"Training, as I say, seems to be the key matter."*

So how can those who work in the field reduce the risk of such incidences cropping up in their own organisations? How can they ensure they're not in front of a coroner reflecting on an avoidable death?

Ms Samuel told delegates that working closely with all relevant parties was the name of the game. *"The bottom line is there needs to be a collaborative approach between different organisations, bearing in mind there is going to be an inevitable overlap in responsibilities. You need to work collaboratively and if in any doubt, ensure that you are putting those measures in place, even if it may well be that someone else is as well.*

"Provide clear training, instructions and updates," she emphasised. *"Consider whether there should be an easy availability of any instructions – for example, should they be near to or on the device?*

"With the portable oxygen cylinder case I had, one of the measures that the trust have put in place is to put a printout of instructions on the wall next to the portable oxygen cylinders as a reminder, in the event that somebody got panicked in the case of an emergency. That is in addition to ensuring that there was training across the board in respect of those cylinders.

"Do you need to provide inspection and maintenance – should that be done by the hospital, or should that be done by the provider of the device? And should there be auditing in respect of both training but also inspection and maintenance?"

While responding to a question from the floor, Ms Samuel emphasised that coroners understand the pressures NHS trusts are under. The delegate asked whether training that was a day out of date would be a source of concern in the event of an incident. *"If you've got training a day or month out of date, but the coroner's satisfied that individual knew how to provide whatever treatment or operate whatever equipment it was, I don't think it's going to be something that overly concerns the coroner,"* she said.

"We are alive to the fact that there are practical issues that will arise. We're not mean people – there [may be] an explanation as to why training may have been missed: it may be for example somebody's off sick and they can't make that but another training session is in place."

But Ms Samuel's speech left absolutely no doubt of the value of regular training on medical devices. And, indeed, no doubt of the value of medical device trainers and educators. As many inquests have made clear, lives can ultimately be at stake.

"Provide clear training, instructions and updates"

PERIPHERAL *vision*

WITH AT LEAST THREE TYPES OF PERIPHERAL CANNULAS BEING USED ACROSS THE ORGANISATION, AND STAFF AND PATIENTS FREQUENTLY MOVING BETWEEN DEPARTMENTS, EDUCATORS AT PENNINE ACUTE WERE WORRIED ABOUT PATIENT SAFETY. SO, AS JANET CLEGG TOLD THE NAMDET ANNUAL CONFERENCE, THEY DECIDED TO STANDARDISE.

Until very recently, Pennine Acute Hospitals NHS Trust was home to an array of peripheral cannulas. Some departments went with the BD Pro Safety; others with Nexiva; still others with B. Braun. It made running IV therapy training sessions quite a challenge.

"We were struggling in the time we had to actually get the main points of IV therapy across," Janet Clegg, the trust's former curriculum development coordinator, told the 2017 NAMDET Annual Conference.

"A lot of the time, we were looking at people from different areas and we were saying: 'Well you do this in your area, you do that in your area, you don't know what I'm talking about because you work in a different site, you actually use this, you set up your infusions differently. Hang on a minute, you use a different cannula so I'll come back to you in a minute'.

"Basically, by the end of it we weren't quite sure what understanding we'd got, there was a lot of confusion, and how can you actually judge what people have learnt from a teaching session like that."

There were concerns that patient safety was at risk as a result; not to mention comfort and experience. *"A typical example: a patient is admitted to A&E on one of the sites, they use a Nexiva cannula. The patient comes in via ambulance with a BD Pro Safety cannula. So A&E take it out and put the Nexiva in, because that's what they're familiar with. The patient goes to the ward, but the ward nurse doesn't know how to use that cannula.*

"So you've got two options there – one they use it, when they've not had any training in that particular device, or secondly they acknowledge that [they've had no training] and they take it out again and replace it with another BD."

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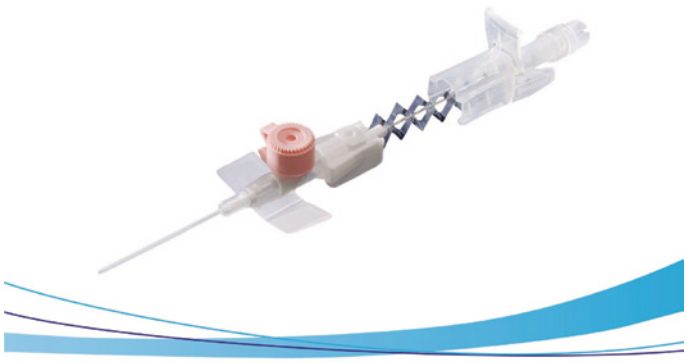
The Pennine Acute Hospitals NHS Trust



She added: *"The competence of staff and the existence of safe practice throughout the organisation was questionable."*

It was a situation summed up by a comment made by one nurse. *"They said I've been a nurse for a long time, I am IV competent, I give IV drugs, but move me to Royal Oldham and I won't be competent because I haven't got a clue what they're doing with the set that they use."*

This scenario wasn't tenable, and so work began to standardise practice across the trust. *"We realised we needed to come up with one approach and it had to fit everybody,"* explained Ms Clegg. *"So we set up a task and finish group. We included people from all different areas across all sites who used the products."*

In the end, the decision was taken to use the BD Pro Safety across the organisation – in part, because it was already the most commonly used. The change was only made recently, but Ms Clegg is optimistic the benefits will quickly be felt.

"We've standardised the practice now, and so we've got improved safety. And we've got improved patient experience – the patient not put into the position where the cannula was coming out, another one was going in, because the nurse was not happy using it."

The experience of running and taking part in IV courses has also been greatly improved. *"We have managed to not only improve the education, but managed to get the three day training down to two days by putting some pre-course reading in. Previously we could not have pre-course reading in IV therapy because there were too many different practices from place to place. Now we can have pre-course reading followed up by a two-day course,"* Ms Clegg explained.

> ***"We've standardised the practice now, and so we've got improved safety. And we've got improved patient experience."***

COULD MEDICAL DEVICES BE A BELLWETHER FOR THE SAFETY CULTURE OF AN ORGANISATION? THAT'S THE QUESTION ELLEN ARMISTEAD, DEPUTY CHIEF INSPECTOR OF HOSPITALS AT THE CARE QUALITY COMMISSION, RAISED DURING THE 2017 NAMDET ANNUAL CONFERENCE IN BIRMINGHAM. HER CONCLUSION? YES. AND SHE SUGGESTED COLLABORATION WITH NAMDET COULD HELP MAKE MEDICAL DEVICES A MORE IMPORTANT PART OF INSPECTIONS OF A HOSPITAL'S PERFORMANCE.

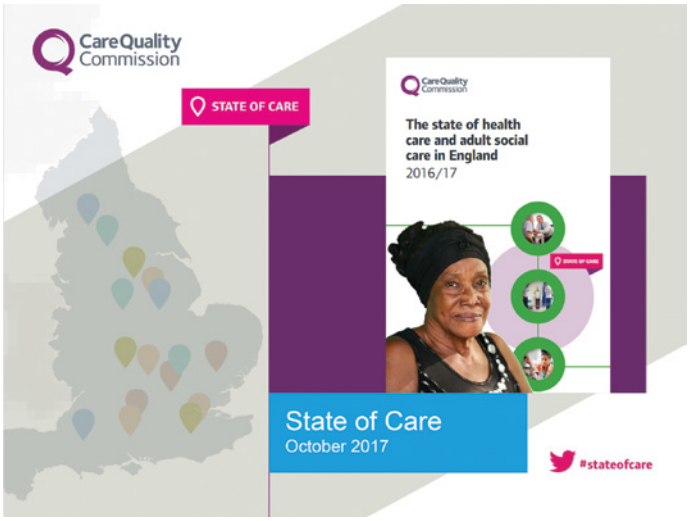
MAKING DEVICES A MARKER OF SAFETY

Ellen Armistead sees plenty of cause for optimism when she looks at the results of the hospital inspection regime run by her organisation. More than half of hospital core services are rated as good by the Care Quality Commission, and around half of overall ratings for NHS trusts are good or outstanding. She's pleased too that when an organisation is rated inadequate, it does generally improve – proof, she believes, that what the CQC is doing really does make a difference.

But there is one important category of key inspection question in which she feels less happy. *"The worrying one for me is – and of course and for all of you in this room will be – safety. So the vast majority of ratings [in that category] sit within 'inadequate' or 'requires improvement'."*

She said some of that was a reflection of the situation in urgent and emergency care services, *"which tend to fare worse than the others for obvious reasons around complexity and demand"*. And she recognised that the health service more broadly is living through very challenging times.

"We've acknowledged in State of Care [the CQC's annual assessment of health and social care across England] that health and care services are at full stretch," she said, adding that *"the results that you've all achieved are an absolute credit to frontline staff and managers"*.



She continued: *"We are very well aware of just how hard and pressured it can be working out there, and we are in absolutely no doubt that much of what you've achieved is down to commitment, passion and a genuine care for those people who use services."*

Ms Armistead explained that the Care Quality Commission was now moving into the next phase of its regulation of hospitals, notably including an ultimate move to a yearly inspection frequency – with all inspections to be unannounced.

"There has been a strong view from both providers and public that all inspections should be unannounced," she explained. Though she noted, with a chuckle, that some nurses had told her announced inspections had the advantage of provoking a sudden replacement of outdated equipment and furniture in time for the appearance of a CQC team.

There is also a desire to focus on *"strengthening that relationship and dialogue with providers"*, allowing the CQC to use a model in which it monitors organisations on a continuous basis. That would include using *"more of our softer intelligence"*; in other words, what patients and staff say about an organisation.

But Ms Armistead suggested there would be value in considering a greater emphasis on medical devices in future inspections. The organisation does already look at this area, she explained, but she queried whether it was in sufficient depth.

"Where we inspect medical devices falls under equipment and environment, and one of the things that I'm concerned about is we probably need to do a bit more work around our assessment of medical devices," she said.

"I'll be speaking to NAMDET at some point around maybe getting some kind of task and finish group together, an expert reference group, to make sure that in your expert view we're covering off all those issues that we need to within inspections."

She said existing work was already uncovering some issues with devices which need addressing. *"Inconsistencies with regular checking of equipment, particularly on resus trolleys, is a real issue in our inspections."*

Perhaps in isolation such issues might not make it to the top of a CQC report, she said. *"But what that kind of thing shows us is the approach to a culture of safety. So if you haven't got a team, if you haven't got a service, that thinks it's the right thing to do to appropriately check your resus trolley, to appropriately check all your medical equipment, then what does that say about that overall culture of safety? So I really do think we could perhaps use the medical device bit more appropriately as a marker of safety culture."*

It was a point she reiterated when a delegate reported fears data on medical devices had been misinterpreted in her trust's CQC report. *"We don't know who's interpreting the data and how it's being interpreted, because all it really was spreadsheets with numbers on it,"* said the delegate.

> ***"Where we inspect medical devices falls under equipment and environment, and one of the things that I'm concerned about is we probably need to do a bit more work around our assessment of medical devices,"***

Replied Ms Armistead: *"I absolutely accept that we don't get into the depth of detail that we need to [on medical devices], and I think we need to address that going forward. I think we should be using medical devices as a much stronger indicator of a culture of safety within the organisation."*

She also urged those working in medical devices to get involved in reviewing data for CQC inspections. *"We send all of the data back to the organisation, and the organisation has quite an opportunity to question any of those factual accuracies. So my advice to you would be to make sure those internal processes are right, because you've got an opportunity there."*

And in response to the point that there are actually no clear national standards on equipment servicing – that it comes down to trusts demonstrating performance on their own policy on equipment – Ms Armistead identified another opportunity.

"In my view, this group needs to really drive this. Because CQC does not set the standards, but we assess people's compliance against any relevant guidance. If the only guidance currently is the trust says x, then that's what we'll assess against. But I do think that's a valid point and maybe in the discussion around an expert reference group, we can pick that up."

Andy Flood, NAMDET board member and conference organiser, queried whether the CQC might also have a stance on the issue of trusts that do not have a medical device trainer or training coordinator. *"It would be how has that been risk assessed, what are your systems and processes if you've not got a dedicated service, what's your workaround for that, is that workaround appropriate,"* said Ms Armistead.

"It's that old 'comply or justify' – if you've not got it, why not?"

So while the CQC may not be able to set the standards on medical devices, it seems it may have an interest in working with those in the field to ensure greater focus on the standards which do exist. And at the end of the conference Paul Lee, chair of NAMDET, said it was a role he was more than willing to assume.

> ***"I'm really pleased that the CQC looked at me and said we need to work with NAMDET on looking at CQC inspections for medical devices – that's a huge piece of work going forward," he concluded.***

COMPETENTLY *using competencies*

SELF-ASSESSMENT IS ALMOST UNIVERSALLY USED IN THE NHS AS A MEANS OF ASSESSING COMPETENCE ON MEDICAL DEVICES. BUT ARE THE FORMS THEMSELVES EDUCATIONALLY SOUND, CONSISTENT AND HIGH QUALITY? MARIE LAW AND TAMMY MARSH AREN'T CONVINCED AND, AS THEY TOLD THE NAMDET 2017 ANNUAL CONFERENCE, IT'S A SITUATION THEY WANT TO ADDRESS.

When Marie Law started to carefully review the competency self-assessment forms used in her trust and others, something quickly became clear. *"A lot of the forms were using language that, from an educational perspective, is not always terribly good practice,"* Ms Law told the NAMDET 2017 Annual Conference.

"They use words like 'appropriate' and they say things like 'describe the key functions'," explained the medical device governance manager at The Pennine Acute Hospitals NHS Trust. *"We're asking people to assess whether or not they felt they could describe the key functions of a device, but there was nowhere that actually stated what those key functions might be.*

"So there was no standard for saying that my understanding of the key functions and someone else's understanding of the key functions were the same. You needed to make more direct reference really to the instruction manual provided by the manufacturer."

There was also concern about the consistency – or lack thereof – between organisations. *"Where the forms said things like respond to alarm codes and warnings, were we all saying that the same alarm codes and warnings were being assessed? And while we were assessing the alarms and warnings, maybe in another trust they weren't,"* said Ms Law.

The reality is that such forms are more or less universally used across the NHS. *"But where each individual organisation was developing a document like this, they weren't necessarily all developing them with the same questions and the same assessment in mind,"* Ms Law explained.

She and her colleague Tammy Marsh, Pennine Acute's medical devices coordinator, decided something needed to be done. But working out just what that something might be wasn't quite so straightforward. After all, neither of them deny that such forms can be useful – particularly for the many people working limited hours in medical devices roles.

"We've had so many conversations with people from various trusts, and many, many times we've been told: 'We already have documents, what's the problem?' Fine, we're not saying you can't use them," said Ms Marsh.

> ***"It's about standardising them, ensuring that the documents were of sound educational practice and that wherever you worked, they were transferable.***

"It's about standardising them, ensuring that the documents were of sound educational practice and that wherever you worked, they were transferable. The nurse transferring between the trusts could take those skills with them, with the evidence that we were all working to the same standards.

"So we've been told numerous times just set up a folder on the website, and everybody dump their documents in there, but it's the quality assurance process behind it that we need."

So that's what they're trying to develop. They envisage a system in which anyone can develop a document against a template, but it is then reviewed and made available to all. *"We're not proposing that half a dozen of us sit and develop these documents for everybody nationally,"* emphasised Ms Marsh.

"What we need is people in this room to develop a document for the device, then make it available. What we're proposing is that the document is submitted to a quality team. Those people will look at the documents; they'll look at that from both an educational perspective and from an industry perspective, so from a clinical user or from a corporate colleague who knows the device inside out."

Once it's been reviewed the document will *"either be accepted and made available for people to use, or returned back to the author with some feedback, some suggested developments, and then it gets resubmitted,"* said Ms Marsh.

In the event of an update to an existing device, the system would alert any potential author of a new self-assessment form that an existing competency document exists. *"It would ask whether you'd like to review that one rather than completely reinventing the wheel,"* explained Ms Marsh.

The system would also automatically alert when a review was needed – *"because things progress very, very rapidly in medical devices, so we need to make sure these documents are reviewed regularly"* – and alert users when new documents are published.

"They'll get an e-mail or some sort of notification," said Ms Marsh. *"And if the document is superseded, the old one will be archived. So for any model of medical device, there will only be the one live document, but the others will be archived so they're still there as evidence."*

The focus on automated alerts is entirely intentional. *"It's a heck of a lot of work to maintain and manage a system such as this,"* admitted Ms Marsh. *"So who's going to do all that admin? Ideally what we'd like is for it to be as automated as possible, so e-mails get sent out without someone having to push a button – that sort of thing."*

What will be required regardless, however, is a team to assess the forms. "*For this to work, we need to recruit a willing quality assessment team, from both corporate and healthcare. NAMDET is all about that combined working between us. We need to carry that through to systems such as this",* argued Ms Marsh, who said she will be putting a call out to all NAMDET regional chairs to talk about the project during meetings.

Yes, she said, it would involve a fair bit of work. But *"the benefits far outweigh that, particularly if you're someone who is part time, or 0.2 of a whole time equivalent member of staff."*

She continued: *"[With such a system] there's consistency and transparency – I think that's one of the key things. Everything is there in front of you, documented. There's a common core content for all medical device assessments, because the structure of the document leads to that very nicely.*

"[There would be] a national structure for suggesting what equipment actually lends itself to self-verification or self-assessment, because not everything will – you may choose not to use self-verification for some things but another trust may. So it's very flexible in that way.

"And it will allow more thorough evaluation of the actual efficiency of self-assessment. The idea of the document is that it's not just for people to sign themselves off; it also acts as a learning needs assessment.

"If the individual picks up one of these documents and ticks no to anything, that's a learning need, so we can then actually put the training in place specifically for their learning need."

"If the individual picks up one of these documents and ticks no to anything, that's a learning need, so we can then actually put the training in place specifically for their learning need."

In drawing the presentation to a close, Ms Law made a simple appeal to the audience. *"Every single place we've ever spoken to are using these documents in some form or another. So I would ask you to go back and have a look at those documents and say, just supposing I were on a teaching training course and I submitted this document as an assignment, would it pass?"*

She said most of Pennine Acute's wouldn't have before she and Ms Marsh started examining them in detail. *"Now because we've started to try and plough our way through, some of them would. But probably a lot of them still wouldn't, because they're not educationally sound, they don't use educationally sound language, because the content of them is just too nebulous. And that's what hopefully we'll be able to do through NAMDET - create something that is just a bit more educationally robust, as good as it can be."*

"So I would ask you to go back and have a look at those documents and say, just supposing I were on a teaching training course and I submitted this document as an assignment, would it pass?"

Registered to attend

The Life Science Industry Register is closer than ever to being a reality, Dr Michelle Dawson told conference delegates.

If you're a plumber or an electrician working at an NHS hospital, you have to fill in an 8 to 12 page document giving your indemnity details, employer details, contract details and much else besides.

If you're a representative of a medical device supplier, on the other hand, you don't have to prove your identification, your training or that you don't have a criminal record. This despite industry representatives' increasing presence in operating theatres while procedures are taking place.

"The complexity of the equipment used in hospitals now means we need representatives to train us; a surgeon does not know how to do a laparoscopic cystectomy on their own with a Da Vinci robot," explained Dr Michelle Dawson, a consultant anaesthetist at Derby Teaching Hospitals NHS Foundation Trust. *"And therefore [industry reps'] involvement in the operations has become greater."*

It's the reason she's been working to create the Life Science Industry Register, a national database of industry representatives and their credentials. Dr Dawson, the clinical lead for the project, told delegates that the standards for the register have been drafted and an application for accreditation by the Professional Standards Authority is pending.

She explained that, once it is approved, the register won't be mandatory. *"So whether it stands or fails is entirely down to the NHS. If industry see value in putting you on it, it will grow and it will thrive, and it will add to patient safety. If industry see no value in putting you on it, they will not register you on it and it will fail.*

"And in 12 months' time, it will either be flying or on its knees – which it's going to be, I really don't know." Watch this space.

The General Data Protection Regulation (GDPR) is due to come into force in May 2018

Get ready for GDPR

The General Data Protection Regulation (GDPR) is due to come into force in May 2018, and means changes in the way in which organisations need to protect information. David Coverdale, senior consultant at health technology firm Egton Digital, said that included the data collected by medical device educators and trainers.

He gave the example of a register taken for a learning session which a hospital then passes onto an equipment supplier. Under GDPR, the hospital would need to ask the explicit consent of the individual to share their information with the industry partner.

"You can ask my permission, and have an audit trail showing I've given you that permission. But if I haven't given you that permission, and you have no evidence of permission, then you shouldn't be doing it." Definite food for thought.

Digital for all

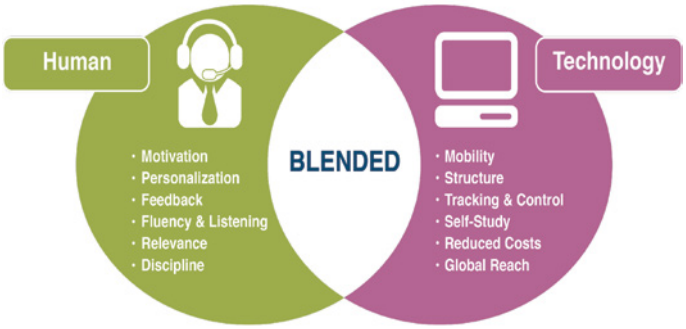
Susan Kennedy of Health Education England is working on projects to increase the digital literacy of the health and social care workforce. Over two million people needed to be supported to gain more digital skills.

"You are all advocates of education and training, and you live in the world of technology and devices, and you know the benefits. And I feel quite confident that you also know how we need to get people fully competent, fully confident, and fully capable."

She said there was a need for digital champions, *"whether they have a badge that says digital champion or whether they're just the person that you feel safe to go to and say how does that work; informal trainers are really important".*

And she made clear that digital now must be the preserve of every individual working in healthcare. *"It doesn't matter what your role is in health or care – you can't avoid being digital any more."*

> ***"It doesn't matter what your role is in health or care – you can't avoid being digital any more."***



Lean on e-learning?

When you're training people on medical devices, is e-learning an option? Or should all lessons be face-to-face? Ginina Houghton, national clinical manager at equipment manufacturer CME Medical, told delegates it wasn't necessarily an either/or.

"The hands-on experience is really important in ensuring the users are confident and competent to use the devices," she argued. *"And classroom training means you've got expert facilitators on hand to answer any questions."*

But it can also be inflexible and expensive – unlike e-learning. She therefore proposed that the audience should consider a blended approach, using both forms of teaching to capitalize on the benefits of both formats.

The incidence and impact of infusion adverse events in paediatric and neonatal populations

This article documents the outputs from an expert consensus panel sponsored by BD and facilitated by Visions4Health. Authors: Sharon Driver and Lisa Jamieson, Senior Consultants at Visions4Health Ltd.

Intravenous therapy is common in paediatric and neonatal nursing care and is accompanied by a range of challenges such as the small and fragile veins of the patient, the requirement for IV lines to be in situ over long periods of time and the inability of the patient to communicate clearly. Therefore, it is not surprising that occlusions, phlebitis, infiltration and extravasation are seen by nursing staff with relatively high frequency. However, because most remain localised and can be resolved with conservative management, the sequelae of infusion events are often underestimated. In reality, depending on the site of injury and severity, extravasation damage can lead to necrosis, tissue loss, scarring, contractures, deformity and loss of limb. The impact of these more severe events on the lives of patients, the morale of the NHS staff who care for them and the demand on the NHS can be significant.

Becton Dickinson (BD) carried out a literature search to evaluate the incidence of local complications related to the use of peripheral and central intravenous catheters in paediatric and neonatal populations, and to identify the risk factors associated with the development of complications related to intravenous catheter use. A literature search was carried out with 2 databases searched (Ovid Medline and Embase) and 266 articles identified and screened. By applying a cut-off date of the year 2000, 15 articles[1-15] were identified as based on routine care in paediatric care settings. These articles documented studies in paediatric and/or neonatal settings using peripheral and/or central lines.

A review of the studies showed significant heterogeneity in approach. The articles varied in the way the data was collected (prospective, retrospective, survey, RCT etc.), the age of patients included, the definition of an 'event' and the data was published as adverse event per line and/or per admission with some patient cohorts having multiple lines in place at the same time.

As expected, the incidence of events from central lines was less than from peripheral lines. For a central line, the reported incidence of occlusion events per line ranged from 1.6%[11] to 12.8%[2]. The data on the reported incidence of extravasation events per line was similarly varied and ranged from 2.9%[7] and 20.6%[10].

The published data on the incidence of events from peripheral intravenous catheters was harder to assess. Danski et al (2016)[3] calculated the incidence of complications in peripheral lines in a neonatal intensive care unit to be 63.15% (n=269), of which 17.84% (n=48) were phlebitis, 69.89% (n=188) infiltration/extravasation and 12.27% (n=33) obstruction. Fonzo-Christe et al (2015)[4] assessed the incidence of extravasation in neonatology and paediatric intensive care units and calculated an extravasation rate of 11.7% (152/1,300) of peripheral lines affecting 17.6% (122/695) of patients.

With the disparity between published trials, a decision was taken to convene an expert consensus panel of 5 senior nurses with experience gained in neonatal and paediatric care in the NHS in England. It is likely that the incidence of events will be healthcare-system specific as the incidence and severity of events will be impacted by the role that nursing staff play in preventing complications and the availability of processes and equipment to alert nursing staff to potential problems. Therefore, the aim of the panel was to assess the evidence and inform the discussion based on clinical experience in the NHS.

To provide context to the severity of occlusion and extravasation events, an initial discussion considered a range of infusion-related complications. Although some infusion-related complications were considered by panel members to be more severe, with serious adverse consequences, e.g. air embolism, cardiac tamponade, these were considered much more rare than occlusions and extravasations. Panel members had strong opinions about the desire to avoid serious incidents related to occlusions and extravasations, due to their relative frequency. Not only can they represent significant harm for the patient, they also impact on service capacity and the ability to support and care for other patients.

The opinion of panel members on the disparity in data from published clinical trials was that the range of event rates was likely explained in terms of how an event was defined. As Danski et al (2016)[3] reported, it was felt that some nursing staff would not distinguish between an infiltration and extravasation. Studies which group these events together could report a higher incidence of events.

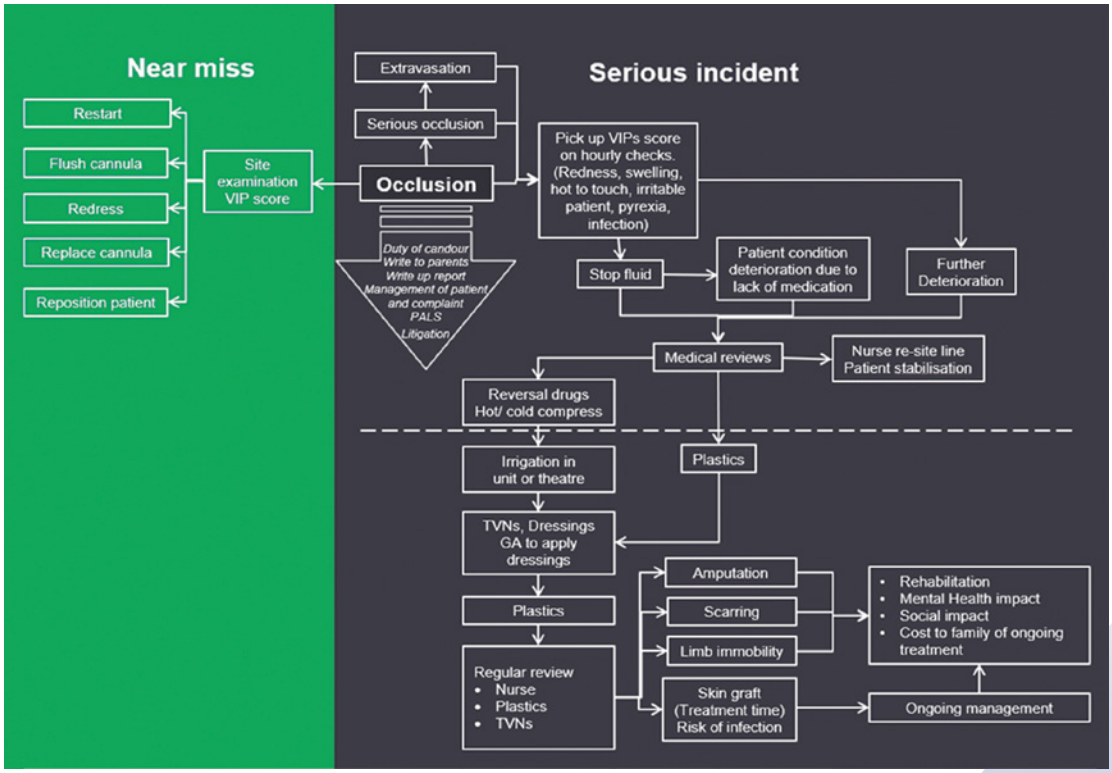
Another factor that could result in disparity in data from published clinical trials was the definition of severity of event used. This could range from 'near miss' events (which may be common and where management would be seen as 'part of the day job') to 'serious incidents' (requiring significant input from wider hospital clinical and non-clinical teams).

Examples of minor occlusions such as, a kink in the tube, dressing placed too tightly, or, positional changes, etc. were

described in terms of happening relatively frequently. These would be dealt with promptly, and would be almost classed as a 'non-event', due to the ability of the nurse to avoid serious adverse consequences. However, more serious incidents would have significant short and long-term consequences, that would require substantial hospital resources from beyond the neonatal and paediatric service, in order to support both the patient and the patient's family. When discussing the published data, the panel expressed the view that the lower event rates could be associated with the reporting of more serious incidents and the higher rates could be associated with a broader definition of an event i.e. 'all cause'.

A patient pathway was developed (Fig.1) to capture the hospital resources involved across the various stages from 'near miss' events to 'serious incidents'. Importantly, some events are seen as unavoidable, e.g. positional change, while others which are avoidable may progress to a more serious incident.

Figure 1 Occlusion and Extravasation Pathway



The role of In-Line Pressure Monitoring (ILPM) devices

Effective patient surveillance is key to the management of 'near miss' events and prevention of escalation to a serious incident. ILPM is a surveillance tool which monitors pressure changes in the IV line. The majority of panel members currently work in environments where ILPM is routinely used. They were therefore of the opinion that clinical practice in their units may differ from that reported in the clinical trials, as use of ILPM can help to reduce event rates - both 'near misses' and 'serious incidents'. Therefore, event rates in the NHS would vary according to whether ILPM was used or not.

ILPM provides an additional resource to support patient safety and reduce traumatic events. This has impacted on staff workload and efficiency of clinical practice. As medicine has evolved and become more complex, nursing staff have been able to incorporate additional and more varied tasks into their working day. This is because ILPM results in less time being needed for monitoring IV lines. Furthermore, panel members suggested that fewer adverse events results in improved staff morale. Panel members were of the opinion that ILPM devices can prevent a 'near miss' from becoming a 'serious incident'. Whilst there are currently cost pressures within the NHS and a necessity to make cost savings, it was felt that the acquisition cost of an ILPM device should not be the only parameter used to judge the potential to make efficiency savings. The ability to use ILPM devices to improve patient safety, and avoid adverse events, should be considered. However, it was acknowledged that this is very difficult to quantify accurately.

All advisers questioned the risk to patient safety from removing the 'safety net' provided by ILPM. They were of the opinion that if ILPM was withdrawn, this would likely increase the rate of adverse events, increase pressures on staff workload, and impact on staff morale. Consequently, where ILPM exists, staff considered it difficult to envisage an environment without it.

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OXYGEN CYLINDERS: Use it right, first time

By Sarah Jennings, Patient Safety Clinical Lead for Medical Devices, NHS Improvement

In the three years 2015-2017, the National Reporting and Learning System (NRLS) received over 400 reports of patient safety incidents where the incorrect operation of oxygen cylinder controls resulted in harm to patients as the supply of oxygen had not been correctly started.

To help prevent further incidents, NHS Improvement recently issued the Patient Safety Alert 'Risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders' (**https://improvement.nhs.uk/news-alerts/failure-to-obtain-and-continue-flow-from-oxygen-cylinders/**). The alert asks providers to determine if immediate local action is needed to reduce the risk, and to ensure local action plans are underway to support staff in preventing these incidents.

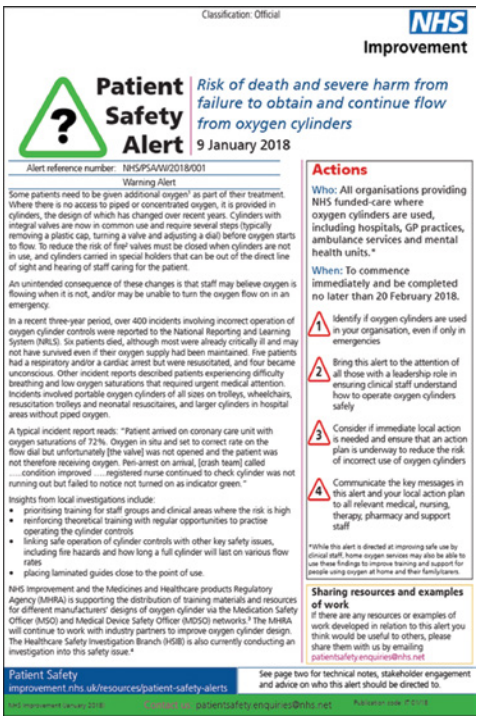
Incidents reported to the NRLS involved portable oxygen cylinders of all sizes, and although they all occurred in hospitals, similar issues could arise wherever oxygen cylinders are in use. This includes mental health units, general practices, care homes, ambulances and patients' own homes.

Medical grade oxygen is an odourless, colourless and tasteless gas which is widely used in healthcare. By the 1950s oxygen was being used for ambulatory patients from small, portable, high-pressure cylinders. Today, modern medicine could not be practiced without the support that oxygen cylinders enable.

However, different design changes from manufacturers to improve the safety of oxygen cylinders have unintentionally resulted in patient safety incidents involving correct operation. These include cases where staff believed the oxygen was flowing when it wasn't, or staff not being able to turn oxygen on in an emergency.

Cylinders with integral valves are common and require several steps before oxygen starts to flow. These steps can be different depending on the cylinder manufacturer and type of valves in use but typically can require removal of a plastic cap, turning a valve and adjusting a dial.

Most staff reporting to the NRLS believed the incident occurred as the cylinder was faulty or empty. However, after local investigation, incorrect operation of the cylinder controls, typically failure to open the valve, was recognised. Without adequate training, operators may assume the same single step required to start piped oxygen flowing (i.e. turning the flowmeter dial) also applies to cylinders.



Classification: Official

NHS Improvement

Patient Safety Alert

Risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders

9 January 2018

Alert reference number: NHS/PSAA/W/2018/001

Warning Alert

Some patients need to be given additional oxygen* as part of their treatment. Where there is no access to piped or concentrated oxygen, it is provided in cylinders, the design of which has changed over recent years. Cylinders with integral valves are now in common use and require several steps (typically removing a plastic cap, turning a valve and adjusting a dial) before oxygen starts to flow. To reduce the risk of fire[1] valves must be closed when cylinders are not in use, and cylinders carried in special holders that can be out of the direct line of sight and hearing of staff caring for the patient.

An unintended consequence of these changes is that staff may believe oxygen is flowing when it is not, and/or may be unable to turn the oxygen flow on in an emergency.

In a recent three-year period, over 400 incidents involving incorrect operation of oxygen cylinder controls were reported to the National Reporting and Learning System (NRLS). Six patients died, although most were already critically ill and may not have survived even if their oxygen supply had been maintained. Five patients had a respiratory and/or a cardiac arrest but were resuscitated, and four became unconscious. Other incident reports described patients experiencing difficulty breathing and low oxygen saturations that required urgent medical attention. Incidents involved portable oxygen cylinders of all sizes on trolleys, wheelchairs, resuscitation trolleys and neonatal resuscitaires, and larger cylinders in hospital areas without piped oxygen.

A typical incident report reads: "Patient arrived on coronary care unit with oxygen saturations of 72%. Oxygen in situ and set to correct rate on the flow dial but unfortunately [the valve] was not opened and the patient was not therefore receiving oxygen. Peri-arrest on arrival, [crash team] called ……condition improved ……registered nurse continued to check cylinder was not running out but failed to notice not turned on as indicator green."

Insights from local investigations include:

- prioritising training for staff, groups and clinical areas where the risk is high
- reinforcing theoretical training with regular opportunities to practise operating the cylinder controls
- linking safe operation of cylinder controls with other key safety issues, including fire hazards and how long a full cylinder will last on various flow rates
- placing laminated guides close to the point of use.

NHS Improvement and the Medicines and Healthcare products Regulatory Agency (MHRA) is supporting the distribution of training materials and resources for different manufacturers' designs of oxygen cylinder via the Medication Safety Officer (MSO) and Medical Device Safety Officer (MDSO) networks.* The MHRA will continue to work with industry partners to improve oxygen cylinder design. The Healthcare Safety Investigation Branch (HSIB) is also currently conducting an investigation into this safety issue.*

Actions

Who: All organisations providing NHS funded-care where oxygen cylinders are used, including hospitals, GP practices, ambulance services and mental health units.*

When: To commence immediately and be completed no later than 20 February 2018.

1. Identify if oxygen cylinders are used in your organisation, even if only in emergencies
2. Bring this alert to the attention of all those with a leadership role in ensuring clinical staff understand how to operate oxygen cylinders safely
3. Consider if immediate local action is needed and ensure that an action plan is underway to reduce the risk of incorrect use of oxygen cylinders
4. Communicate the key messages in this alert and your local action plan to all relevant medical, nursing, therapy, pharmacy and support staff

*While this alert is directed at improving safe use by clinical staff, home oxygen services may also be able to use these findings to improve training and support for people using oxygen at home and their family/carers.

Sharing resources and examples of work

If there are any resources or examples of work developed in relation to this alert you think would be useful to others, please share them with us by emailing patientsafety.enquiries@nhs.net

Patient Safety improvement.nhs.uk/resources/patient-safety-alerts

See page two for technical notes, stakeholder engagement and advice on who this alert should be directed to.

Operators were also sometimes confused by aspects of the cylinder's design. For instance, no clear indicator on the valve to show open/closed positions, the plastic cap hiding controls, or the green indicator showing a full cylinder being misinterpreted as an indicator of active flow.

When the flow rate dial is operated on cylinders that have previously been used, but not vented before next use, a 'hiss' of flowing oxygen can be heard for a few seconds even with the valve closed. This can reinforce a member of staff's belief that they have turned the flow on.

In addition, users also found it difficult to estimate how long a cylinder would last during an episode of care.

The focus of our Patient Safety Alert is for all organisations to review what mechanisms are in place to operate oxygen cylinders appropriately, whether in an emergency, or for routine transfers of care.

Localised training may be required and resources including pictorial diagrams may also be useful.

Specific sequences of activating oxygen cylinders could be incorporated into mandatory BLS training.

Organisation transfer policies should establish who is responsible for activating and maintaining oxygen flow if a cylinder is required.

Information on flow duration depending on cylinder size and flow rate can be sourced from manufacturers and should be made available.

Coinciding with the issuing of this alert, the Healthcare Safety Investigation Branch (HSIB) has also launched an investigation into the design and safe use of portable oxygen systems (**https://www.hsib.org.uk/investigations-cases/design-and-safe-use-portable-oxygen-systems/).**

We hope that by highlighting these issues in MDET, as well as through cascade to Medical Device Trainers, MSOs and MDSOs, and the usual alert streams, will help in promoting both the safe and accurate use of oxygen cylinders. We also encourage the sharing of any local initiatives and useful feedback around this issue via our patient safety. **enquiries@nhs.net** email address.

Sarah Jennings is the new Patient Safety Clinical Lead for Medical Devices at NHS Improvement, on secondment from Salisbury Foundation NHS Trust, where she is the Medical Device Safety Officer and Trust Decontamination Lead.

NEW YEAR RESOLUTIONS

Following the Christmas festivities our minds turn to New Year resolutions and how long we can keep up the good work of reforming ourselves through weight loss, more exercise or reviewing our personal wellbeing, and our work life balance.

Dawn Stott, CEO

Personally, I haven't made any New Year resolutions this year, not because I think I'm perfect and one can't improve on perfection (as I told my husband) but I decided not to put myself under any undue pressures. This in itself is a resolution, a promise to myself that I will do my best for me by putting in place some building blocks for positivity, which brings with it an ability to move forward with those dreams and goals that we put on hold or don't even believe we are capable of achieving. The ones that we continually nudge forward each year and leave unfulfilled.

Coaching gurus tell us that when we hold positive thoughts in our minds we are strong emotionally, physically and mentally. These positive thoughts, in true Peter Pan style, are our tools to improvement, or for Peter Pan – flying! This isn't just for ourselves but for those around us – just as smiles are contagious, so is positivity.

Make a list of all the times you have succeeded; moments you are most proud of or compliments people have given you. What qualities did you demonstrate in those moments? Were you brave, kind, sincere, positive? Did you at that moment believe in yourself?

If you are positive, whatever you believe will be true, you will find evidence to prove yourself right. However, if you hold on to negativity, whatever you believe will be negative and you will find evidence to prove why things went wrong and why everything bad happens to you.

Individuals can be incredibly talented and yet if you don't have self-belief then they will not execute their actions as well as they really could. In order to create compelling beliefs we have to really challenge the self-limiting beliefs that manifest themselves in our minds. Ask yourself, are they really true? Why do I believe they are? What would I do if I knew they were wrong?

Great self-believers have the striking ability to push aside any obstacles to their goals; obstacles on which most people would have given up. Your belief is what can make or break you stepping into your goal. Bring into conscious awareness your limiting beliefs (I am not clever enough; I do not have enough...; I am not as good as others) and think about what belief you will need to have that is vital to you achieving your goal – **I NEVER GIVE UP; I HAVE THE DETERMINATION TO SUCCEED; I AM WILLING TO LEARN; I AM POWERFUL BEYOND MY KNOWLEDGE.**

I urge you therefore, to think of limiting beliefs as thoughts alone, they are not real. Build some compelling beliefs to catapult you forward and empower yourself to be better at what you do.

Our positive thoughts are our tools for greater success. Resistance to anything is the same as trying to change a picture once it has been transmitted – it doesn't work. By resisting what has already happened you add more energy, thus allowing it more power.

> *Mother Teresa once said;*
> ***"I will never attend an anti-war rally. If you have a peace rally, invite me".***

What a powerful message, don't throw your thoughts and efforts into something that cannot be changed because it is already happening: focus on what you can change.

How many times have you done something that hasn't worked out and you have spent days brooding and wishing you had done it differently. STOP – look back, revisit why it went wrong and focus on what you could have done to make the outcome different – use your mistakes to improve next time and bolster your self-belief.

AfPP are holding a Leadership day on **Saturday 24 February 2018** at the **NHS International Centre for Life in Newcastle upon Tyne.** The day will explore how we can find our own leadership qualities rather than look to others to lead, discussing followership and how followers can also be leaders, and to examine the challenges of leading from different roles within the team. It will look at managing different and sometimes challenging personalities within a team.

Designed to inspire professionals, the day will allow delegates to share best practice and knowledge with their peers. We will look at tools and techniques to help us identify how good practice can be shared and how spreading good practice in the perioperative environment can support safer patient outcomes. We will explore what part we all play in leadership and develop a real life working plan for all delegates to take away and use when in their working environment.

The day is aimed at practitioners working in supervisory or managerial roles; however, it will provide knowledge and insight for those practitioners working towards a higher grade.

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or call Kelly Squires on **01423 881300**

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Send your answers to: **editorial@mdetjournal.com** and include your name, job title and work organisation / location

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2

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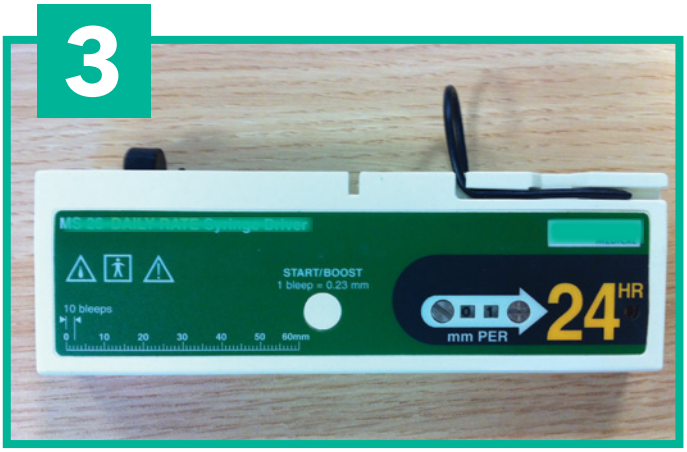

Competition terms and conditions:
- The competition is open to all readers of MDET. Send your answers to editorial@mdetjournal.com
- Closing date for entries is 30th March 2018
- The winner will be randomly drawn from all the correct entries received, or in the case of no fully correct entries, the most correct answers.
- There will be one prize of a £50 online store voucher for the winning entry drawn
- The winner will be announced in the next issue of MDET and will receive their prize before the issue is published
- The ultimate judge of correct answers will be the competition author Paul Lee
- The competition is not open to employees of Specialist Publishers Ltd. or directors of NAMDET or their families
- No purchase is necessary to enter
- This competition is run by Specialist Publishers Ltd., Marchamont House, 116 High Street, Egham TW20 9HB

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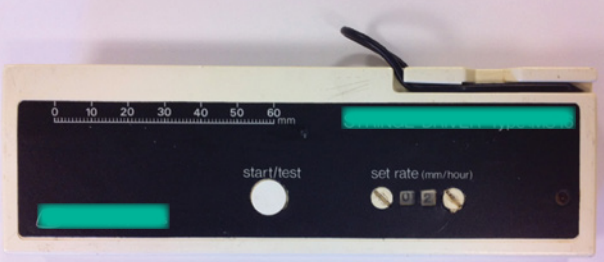
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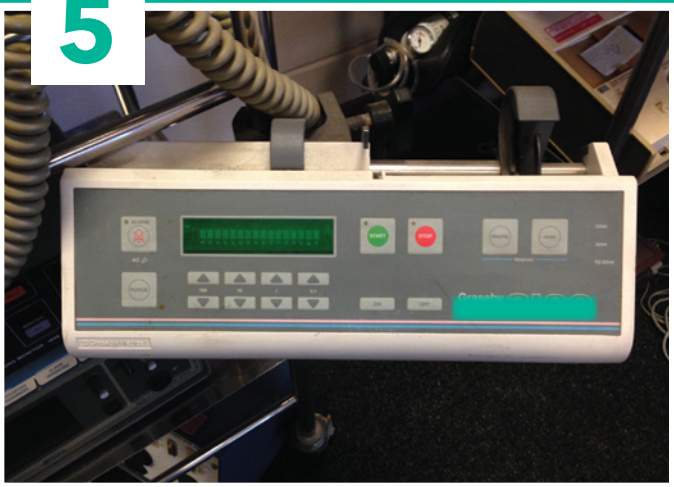

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MANUAL
Basic Cycle = 1 Minute
X10
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AUTO CRESCENDO
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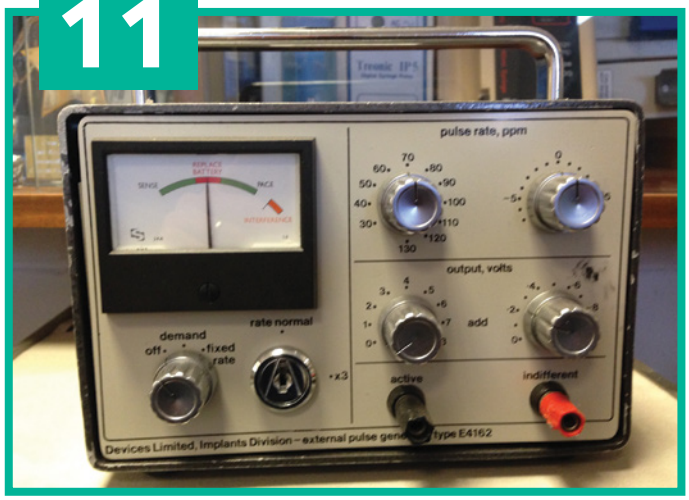

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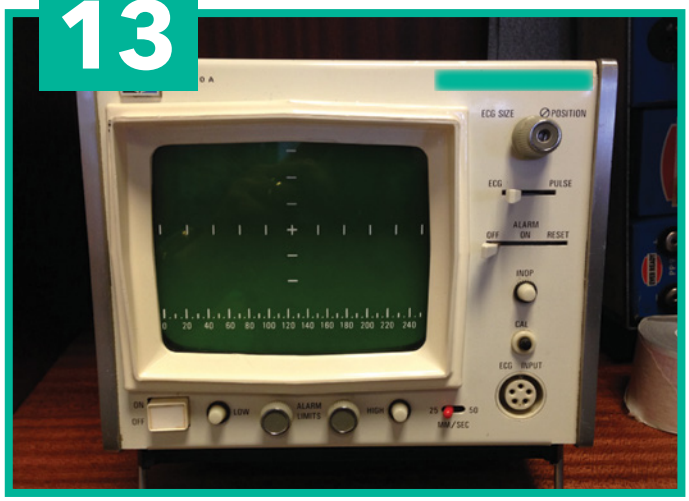

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At last - National Occupational Standards for medical device company representatives

For the first time, there is now a National Occupational Standard for medical device company representatives present in hospital clinical areas. Credentialing asks company representatives the question – "do you have hospital access or theatre access training?" Now the question should be – "do you have the National Occupational Standard in line with other hospital professionals." It is this standard that will mitigate risk for hospitals. Diane Irvine, CEO of Healthcare Skills International outlines this significant step forward.

Education programmes for medical professionals delivered by Healthcare Skills International have now been recognised as National Occupational Standards (NOS). Cogent Skills, who are responsible for setting skills standards on behalf of the UK's science industry employers, completed the exercise.

Healthcare Skills are already an approved education centre, delivering a comprehensive range of online and classroom-based externally validated, competence-based qualifications to the healthcare industry and medical profession. The NOS status has been mapped to the company's Hospital Theatre Access and Hospital Access training programmes, which are tailored to employees of medical device companies who are required to be present in clinical areas – including operating theatres – to provide technical support and expertise to medical teams.

NOS specify UK standards of performance that people are expected to achieve in their work. Approved by the UK and devolved government regulators, they are available for almost every role in every sector in the UK. NOS are used as the building blocks for many vocational qualifications and are competency-based tools, which are statements of the skills, knowledge and understanding needed for employees to carry out particular job roles or functions. NOS have international status and are recognised worldwide.

Having a NOS for medical device company representatives present in hospital clinical areas allows medical device company employees to demonstrate that they have reached the required standard of professionalism and technical competence. This, in turn, positively impacts on patient safety.

Cogent Skills works across the science sector, representing life sciences, pharmaceuticals, biotechnology, medical technology and consumer healthcare. Healthcare Skills Theatre Access and Hospital Access courses – aimed at medical device sales people, clinical educators, product specialists, clinical support staff and NHS staff – are now available via the Cogent Skills website (cogentlearn.com).

The Theatre Access programme is a two-day course that develops the knowledge and skills that hospital management expect of medical device industry personnel entering, assisting and providing verbal/technical input within clinical areas. It includes practical workshops in an actual theatre environment, risk assessments, practical skills assessment, and it is delivered at venues at Weetwood Hall, Chapel Allerton Hospital in Leeds and Moller Centre, at Addenbrookes Hospital in Cambridge.

Cogent Skills Standards Manager Ian Lockhart complimented Healthcare Skills on their achievement:
"It has been a pleasure to work with Healthcare Skills to map their qualifications to National Occupational Standards. We support the passion shown by Healthcare Skills to enhance professional activities in the sectors in which they operate and their drive to align their qualification for healthcare and medical device professionals with national legislation and regulations."

The Association of British Healthcare Industries, who are the industry association for the medical technology sector in the UK, warmly welcomed the initiative. Andrew Davies, ABHI's market access director, said:
"ABHI congratulates HC Skills International on their Theatre Access and Hospital Access programmes gaining National Occupational Standards status. Medical device representatives often play a crucial role in supporting the surgical team through technical and product advice. Meeting appropriate standards of performance is an important factor to assure that staff have the necessary knowledge and skills to effectively perform their function."

Further support has come from Barema, the trade association for anaesthetic and respiratory device suppliers, who are also training partners of Healthcare Skills. The organisation's chair Nicki Dill said
"We are proud to work in partnership with HC Skills International and extend our sincere congratulations to everyone involved in achieving National Occupational Standards. This major achievement results from their passion, tenacity and commitment to enhance professional activities in the healthcare sector, with the alignment of these qualifications for medical device professionals with national legislation and regulations."

Healthcare Skills, who are based at West of Scotland Science Park in Glasgow, have delivered training programmes to tens of thousands of medical professionals and those working in the medical device industry for more than 10 years.

SELFIE

Name: Graeme Kirkpatrick

Age: 50

Role: Head of Patient Safety (Advice & Guidance) for the national patient safety team at NHS Improvement

Family:
Married to Sue (a rheumatology nurse specialist), two kids Ross (19, currently working as a Pharmacy Assistant but wants a career in health & fitness) and Abbie (17, hoping to go to uni to study Psychology)

Hobbies/interests:
Watching sport (especially my son's football team), walking, gin and the occasional game of curling.

What is your working history that led to where you are now?

I'm a pharmacist by background and have worked in acute hospitals since I qualified in 1990; mainly in cancer services. I worked in Scotland and Wales before moving to the North East of England in 2002 to be closer to family as our kids were 3 and 4. I was appointed Chief Pharmacist in Durham and stayed with the trust until March 2017 when I moved to NHS Improvement. As well as being Chief Pharmacist I also had a spell as Divisional Manager for Clinical Support Services and took on additional roles as Clinical Governance Lead for Acute & Emergency Medicine and Associate Director for Mortality. A desire for a change and my passion for patient safety led me to apply for my current role.

What is your responsibility as Head of Patient Safety (Advice & Guidance)?

I oversee a team of specialist staff who, based on reported patient safety incidents, work with colleagues across the NHS and other organisations to produce advice and guidance to the NHS including all Patient Safety Alerts. The intention of this guidance is to mitigate the identified issue from reoccurring and produce sustainable improvement. We have clinical leads for medicines safety, medical specialities, surgery, maternity and neonates and of course medical devices.

What one thing would you want MDET readers to understand about the national patient safety team?

The national patient safety team are the only people in the NHS that have sight of the 14 million incidents held in the NRLS database, with 150,000 new incidents reported every month. As a result, we are the only ones who have the insight into the new and under-recognised issues that may be occurring in the NHS as a whole, which is the reason why we target these issues for patient safety alerts.

What do you find most challenging in your role?

Probably the biggest challenge has been moving out of a role within a single profession, where I was Chief Pharmacist and felt relatively comfortable, to taking on responsibility for an element of patient safety across all areas of the NHS. I am therefore very thankful to have a team of experts within the patient safety team at NHS Improvement who I can call upon when I need an answer to one of my numerous silly questions. Thanks to Paul Lee previously and now Sarah Jennings for offering me that support in relation to medical devices.

What has been your most significant accomplishment in your work?

As I've only been at NHSI since March I'm not sure I've had any 'significant accomplishments' in this job, yet! Across my career, I would say that my biggest accomplishment was setting up a pharmacy department within the new North Wales Cancer Centre at Glan Clwyd Hospital; this involved helping to commission the new build, recruit the staff and create the processes and procedures to establish a new dispensary, aseptic, radiopharmacy and clinical service.

What things about your work frustrates you the most?

In general terms, silo working frustrates me. If we are truly going to improve patient safety, and the NHS as a whole, then we need to collaborate, share and be happy to plagiarise across professional and healthcare boundaries.

What do you most want those working with medical devices in the NHS to understand?

Where to start! Firstly, that staff should not use, or be expected to use, any piece of medical device until they are truly comfortable with how it works. Ideally this should be through formal training, but if not, tell your line manager or ask your local Medical Device Safety Officer; they're a friendly bunch! Secondly, report any work arounds. The difference between 'work as imagined' and 'work as done' is critical to improving patient safety, so if staff are using work arounds because of issues with medical devices tell someone so that guidelines and policies can be re-examined.

What would you like to see medical device manufacturers do more / less of?

Engage with staff and patients. Work with frontline staff, test the usability of devices in real-life situations before they are introduced onto the market, and then seek frontline opinion on usability regularly (post implementation) to update and improve the device.

What one piece of advice have your received that you feel has been significant to you and worth sharing with readers?

The 5 Ps – perfect planning prevents poor performance. If time allows, it's always important to do the ground work and prepare properly for whatever piece of work you plan to tackle; whether that's a presentation, a project or a major piece of change management.

What topics would you like to see covered in MDET in the future?

MDET is an important resource for the national patient safety team to promote key messages to the medical device education and training community. So basically, we need to work with NAMDET to ensure that as new issues come to light through the work of the national team, these topic are covered within the journal.

If you could be any fictional character who would you be and why?

Hercule Poirot – whilst I can't pull off the moustachioed look, a man with such pedantic tendencies and attention to detail is a man after my own heart!

If you had not gone into the career you have, what would you have been instead?

Always wanted to be a Farmer when I was young – Farmer / Pharmacist not so dissimilar!

If you were granted three wishes what would they be?

For Scotland to win the rugby world cup … at Twickenham, for my kids to be healthy and happy in whatever career they choose to pursue and to enjoy a long retirement (when it comes) in a cottage by the sea with too many cocker spaniels – not necessarily in that order.

What's your favourite book or film and why?

All of the Rebus series by Ian Rankin – exceptionally well written and always take me back to my home town of Edinburgh.

What's your favourite song and why?

Anything from the 80s that reminds me of my carefree student days in Aberdeen.

What / who is the person or thing that has inspired you the most and why?

The kids with cancer, when I worked as a clinical oncology pharmacist at the Royal Hospital for Sick Children in Edinburgh. Their zest for life and positivity, despite their situation, always put things into perspective and still maintains my drive to ensure we never lose sight of the patient.

ABOUT TURN

John Byrne began his career as an electronics technician in the army, working on long range weapons and tanks. Some thirty years later, he's a trainer working with healthcare colleagues up and down the country. He tells Claire Read how a posting to a naval hospital in Gibraltar offered a start in working with medical devices, and how life outside the army differs from life within it.

On the first day of his first job in medical devices, John Byrne marched over to his boss's office to introduce himself. He stopped neatly in front of the desk, drew himself up to his full height, and greeted his new colleague. The response wasn't very friendly. *"The guy looked like a boxer, proper scary,"* remembers John, *"and he said: 'Get out of my office!'"*

If you're thinking that's not the sort of response of which an NHS human resources manager would approve, then fear not. John wasn't in a NHS hospital. He wasn't even on the British mainland. No, he was in a naval hospital on the British territory of Gibraltar. And, as a member of the army, was finding out that in the navy officers aren't as keen on the marching and halting that was standard practice in his sector of the armed forces.

"I MARCHED OUT OF THE OFFICE AGAIN, AND HE CAME OUT AND SAID: 'DON'T EVER DO THAT TO MY CARPET AGAIN.'"

John had started off in the army as an electronics technician. *"So the first two years were spent training up in electronics. Then I got posted out to my first unit in December 1988, with the 45th Field Regiment Royal Artillery and the Third Royal Horse Artillery, working on the long-range guns. My job was to make sure the rounds went on target for 25 - 26 kilometres away."*

His next posting with 4th/7th Royal Dragoon Guards, the 5th Inniskilling Dragoon Guards and the Royal Dragoon Guards saw him working with tanks, *"First of all I was in Colchester, then I was working with tanks in Germany. I was always away because the tanks were always away, off on exercises, practising tank manoeuvres. So, we were always out in the field. I spent some time in Canada too."*

It was when he was completing his Class 1 course in electronics – a more advanced programme offered by the army – that the idea of working with medical devices first occurred. *"While I was there, I met the guys who did the training for medical and dental. And they said that I had to come top in my Class 1, and then I could go out to do medical devices training. Which I did.*

"So I did a six month conversion course, and then I got posted out to Gibraltar, working in the Royal Naval Hospital. I was the first army ever to do the job, which was to service all the hospital equipment. Most of it I'd never seen before, because I'd come straight off a course, straight to working there. Of course it was completely different to tanks!"

But he was aware his new area of focus was something which gave him a prospect of a career even once he left the army. *"I thought I would have a trade then – they've got medical equipment on civilian street. I was looking short term at leaving the forces and working in a hospital."*

The departure from the army didn't happen quite as quickly as John had initially envisaged, though – not least because he spent much longer in Gibraltar than had originally been anyone's intention.

"I was only meant to be there for one year. But I phoned up after my first year and said: 'Could I stay out in Gibraltar?' The hospital was supposed to be closing, but it had been closing since 1979," he says with a laugh. *"They let me stay for two years. The second year I got my commanding officer to write a letter to keep me there, but then the third year I tried it and they said 'get lost, you're coming back!'"*

He found himself in Tidworth, in Wiltshire. *"I was working in a big warehouse called the Medical Supplies Agency,"* explains

John. *"My job there was to inspect equipment; making sure the equipment that is going out to [military] hospitals works, and anything that's going out to operations. There's stuff that's been bought brand new going out to different places abroad, and equipment stores that could be called out.*

WOULD INSPECT ALL THOSE DEVICES AND MAKE SURE THE KIT WAS ALL COMPLETE AND READY FOR OPERATIONS."

During this time, John also had 2 detachments to both the Falklands and Kosovo. Getting a bad case of itchy feet, John jumped at the chance for a posting to Brunei – even if he wasn't quite sure it was a perfect match for his skills. *"It wasn't within my trade; it was in telecommunications. I went out there to do a mixed role of telecommunications repairs and also medical and dental."*

Success in getting medical equipment through the yearly quality inspection meant the mix was more heavily weighted in that direction that the other. *"When I went out there, I had two months to prepare for the next quality inspection, and I got us through with a pass. It's only pass or fail – it goes red, amber, green. I got a green. I was therefore able to stay in the role more on medical/dental rather than working on telecommunications."*

He was also able to do an awful lot of travelling. *"Brunei was a nice post, I got to see a lot of nice places – I had lots of holidays out there: Australia, Hong Kong, Singapore, various places in Malaysia. I played in the rugby team there as well, rugby 7s, and we went off on tours outside of Brunei as well. So, it was a very nice posting."*

His next couple of roles saw John focus solely on telecommunications – firstly as an advisor, and then in Germany as an equipment inspector – but his final job in the army did bring things back to medical.

"I was posted to my final tour in the Royal Hospital Haslar," explains John. *"My job there was basically to close down that hospital. It was the last remaining mainland hospital, and it was being closed down. So I saw it through its last quality inspection. We got a green, and then I could concentrate on leaving the armed forces and becoming a worker."*

Which he promptly did, taking on a role at a healthcare technology management company EBME Limited. *"My job there was looking at medical devices training. And it was something I hadn't done before - user training. I was working at a couple of sites, and the first hospital I was at, they were filling in paperwork one per person per device. So, if they had 50 staff and 50 devices, you had 2,500 pieces of paper. I reduced the amount of paper by getting it down to just one paper per person."*

It was a system which subsequently earned the praise of the NHS Litigation Authority during an inspection, and John

continued with the company for almost seven years. After a stint as an Electrical and Biomedical Engineering (EBME) manager in an NHS trust, he went back into the private sector in May 2016. *"I work for Arcomedical Infusions Limited, doing field service repairs, clinical training and technical training."*

He also plays an important part on the national board of NAMDET. After serving as the first chair of the London region, which became London and South East, he's been NAMDET secretary for the past four years and has now taken over as treasurer.

Asked about how his time in the army has informed his career outside it, John points to the value of explaining why a device needs to be used or cared for in a particular way. He remembers reading material on the devices he had to inspect, and suddenly understanding why he'd previously been told to do something in a certain way. *"I was thinking: if only they'd have explained that, then I would have done it."*

John tries to make that sort of explanation part of his role now. *"When I started to do my quality inspections, everywhere I went they were failing. And they were failing badly. What I suggested to my boss was that I actually do a pre-inspection – so I go along and do a day, meet up with the people I was going to be inspecting, and then do a pre-quality assessment of their department. And I explained what they needed to do, and also why they needed to do it. So, when I came to do an inspection properly within three months' time, they were starting to change things and make things right, and I wasn't failing people after that, well not failing as many."*

He continues: *"Rather than just say you have to do this because I say so, it's about explaining why you should be doing it. When I do an audit report of a hospital, I don't just say such and such weren't doing this. I say the reasons they weren't doing it, the explanation why we need to be doing it. For example, the MHRA Managing Medical Devices [guidance] says this, or the Health and Social Care Act says that. It all adds credence to the report and people see why they need to be doing it."*

It's just one way in which he's changed his style of communication since leaving the armed forces. Because while the devices he came across in his previous life are very similar to those he works with now, the culture definitely isn't.

"I'VE HAD TO ADAPT THE WAY I SPEAK TO PEOPLE AND MANAGE PEOPLE. ARMY MANAGEMENT IS VERY DIFFERENT TO CIVILIAN MANAGEMENT – *army management is basically 'can't means won't, and won't means jail'. Quite easy. Whereas when you come out of the military into civilian life, you've got to treat people differently – you can't shout! I think when I first came out I needed to calm down my military side. I changed the way that I spoke to other people."*

And he certainly doesn't march into offices, come to a halt, and do a right turn when leaving any more. Someone once told him it ruins the carpet.

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New Wave of Equipment &Technology Being Backed By NHS England

As part of the NHS Innovation Accelerator (NIA) programme, the next wave of 11 ground-breaking projects being backed has been announced. These will be promoted across the NHS by the 15 NHS Academic Health Science Newtowrks (AHSN) to support their adoption 'at scale' across the country. Those specifically highlighted by NHS England are:

- **RespiraSense:** A wireless device that measures breathing through chest and abdomen movements delivering highly accurate, continuous data. This might aid the early detection of and more effective treatment of conditions such as Sepsis and Pneumonia as well as Cardiac Arrest.
- **Home monitoring of hypertension in pregnancy (HaMpton):** Allows pregnant women at risk of pre-eclampsia to input blood pressure readings and urine test results into an app, then answer a set of questions to help identify the condition. The app links with a hospital computer system where the data can be monitored by clinicians in real time.
- **WaitLess:** An app that shows patients with minor injuries where they can go to access the quickest treatment, using real time waiting times and traffic/travel information.
- **Dip.io:** Provides patients with clinically accurate urine analysis from home in a matter of minutes, helping to identify Chronic Kidney Disease and UTIs as well as pre-eclampsia in pregnant women. Patients perform a dipstick test at home and then, using the app, take a picture of the dipstick against a special backing. The analysis is then sent through the app directly to the patient's doctor for diagnosis.

Simon Stevens, NHS England chief executive, said: *"Modern medicine is on the cusp of a huge shift in how care is delivered, and practical innovations like these show how NHS patients will now directly benefit. More tests and patient monitoring will be done at home or on the move, without the need to pitch up to a doctors appointment or hospital outpatients."*

NHS England

Confirming removal or flushing of lines and cannulae after procedures: NHS Improvement Patient Safety Directive Alert

The risks of residual anaesthetic or sedative drugs being left in intravenous (IV) lines and cannulae unless they are effectively flushed at the end of the procedure, have been known for some time. Indeed, a Warning Patient Safety Alert 'Residual anaesthetic drugs in cannulae and intravenous lines'[1] was issued in April 2014. That alert required local system review and, if required, the development of an action plan to reduce the risk of such incidents occurring.

Residual drug being inadvertently introduced into the patient's circulation, causing effects such as muscle paralysis, unconsciousness and respiratory and cardiac arrest, has been included in 58 incidents reported to the National Reporting and Learning System (NRLS) in the three years since the 2014 alert's completion date. Some of these incidents are occurring from lapses in identifying and flushing all IV lines and cannulae intended for further use. Additionally, these incidents are also resulting from failure to remove cannulae specifically inserted to administer anaesthetic and sedative drugs, at the end of a procedure. When two or more IV lines or ports are connected to the same cannula there is the additional risk that flushes may not remove drugs that have back-tracked up one of the lines or accumulated in the additional space within multi-lumen connectors.[2] The risk of this backtracking can be reduced by using infusion sets and ports with one-way valves.

NHS Improvement has identified a range of local procedures which help ensure patients do not return to wards with cannulae or IV lines in place that may contain residual drugs. They suggest: 'The most effective of these centre on adding prompts to existing procedure documentation and at patient handover from clinicians in the procedural area, confirming that all cannulae and IV lines that may contain residual drugs have been fully flushed or removed.' These actions are supported by the National Safety Standards for Invasive Procedures (NatSSIPs).[3]

In response, a new directive (Alert reference number: NHS/PSA/D/2017/006) was published by NHS Improvement in November 2017 and requires all organisations to implement the 4-point action plan shown in figure 1.

References:
1. NHS England Patient Safety Alert NHS/PSA/W/2014/008: Stage one: Warning. Residual anaesthetic drugs in cannulae and intravenous lines. 14 April 2014 https://improvement.nhs.uk/news-alerts/residual-anaesthetic-drugs-cannulae-and-intravenous-lines/
2. Medicines and Healthcare products Regulatory Agency. Medical device alert - Intravenous (IV) extension sets with multiple ports - risk of backtracking (20 September 2010) https://www.gov.uk/drug-device-alerts/medical-device-alert-intravenous-iv-extension-sets-with-multiple-ports-risk-of-backtracking
3. NHS England National Safety Standards for Invasive Procedures. 7 September 2015 https://improvement.nhs.uk/resources/national-safety-standards-invasive-procedures/


NHS Improvement

Patient Safety Alert

Confirming removal or flushing of lines and cannulae after procedures

9 November 2017

Actions

Figure 1.

Actions

Who: All hospitals and other units that undertake surgical interventions or other procedures involving anaesthesia or intravenous sedation for NHS-funded patients

When: To begin as soon as possible and be completed by 9 August 2018

1. Identify a named individual to take responsibility for co-ordinating the delivery of the actions required by this alert.
2. Amend the Sign Out section of the WHO Checklist or equivalent in local use to include confirmation that before a patient leaves the procedural area:

   a) All IV administration sets and extension sets without active flow have been removed.

   b) Any multi-lumen connector without active flow through all its arms is removed; or, if this is not possible because a patient cannot tolerate even brief interruptions to essential drug or fluid delivery, that all arms have been adequately flushed.

   c) All cannulae have been identified and either removed or adequately flushed.
3. Include in local documentation for handover from procedural area to recovery, and recovery to the subsequent place of care, the requirement for documented and verbal confirmation that lines not in active use have been removed and multi-lumen connectors and cannulae removed or flushed.
4. Establish ongoing systems of audit to ensure these barriers are maintained.*

*This may be part of existing audit systems to support the implementation of the WHO checklist and NatSSIPs.

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