

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



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# MDJET

The Journal of Medical Device Education & Training

Teaching  
self-administration

Recording  
competencies

South Wales  
to Serbia

Voices:

*NHS*

*Improvement*

*Science Council*

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**Mike Peel**  
NAMDET Editor



# FIRE UP THE QUATTRO...

**"Get ready boys. Fire up the Quattro." This will mean nothing unless you were a fan of the cult TV programme. Do you remember it? It starred Philip Glenister and takes us back to the 80's. But I digress already!**

**A**s we enter the Autumn season, the NAMDET Board and Working Group have had their 'noses to the grindstone' putting the Birmingham Conference together. As you will already know this will be our 6th annual conference and we are again at the Birmingham Holiday Inn on Thursday 2nd November. This year's theme is around improving safety through a competency approach. The aim of this annual event is to bring together NHS, industry and other organisations to share knowledge and expertise in Medical Device Education and Training. This year the conference team have again been led by Andy Flood and this will be Andy's fourth, or quarto colloquium. Andy has decided to step down from leading the organisation team in 2018 and so if you would like to get involved, or have ideas for speakers, then get in touch and volunteer. This edition of MDET incorporates the conference programme (just turn upside down and read from the back, or is it the front?!), so please do take a look at this year's impressive array of speakers and topics. This year also sees our largest exhibition to date and we very much thank the many commercial colleagues whose support is so crucial for the success of the conference.

November also sees NAMDET working alongside Patient First at London's ExCeL on Tuesday 21st & Wednesday 22nd November. We have been invited to provide a series of educational talks in our own NAMDET 'Medical devices and medicines safety theatre'. Speaking will be NAMDET members, supported by medicines colleagues,

giving a cross section of both medicine and medical devices' problems and solutions. You can also meet members of NAMDET at our stand J50, next to the theatre. Patient First is the UK's largest patient safety event and will once again be supporting those operating within the NHS and independent healthcare sectors, communicating practical advice to catalyse action for change. More information on attending for free can be found at: <http://www.patientfirstuk.com>

So back to the exciting and packed fourth edition of our MDET journal. This MDET issue Quattro has articles on the challenges of storing competency records, training patients for home self-administration of IV drugs and a look at what happens to used and old medical device equipment in South Wales, as well as our usual Voices, Selfies and News.

**WE NEED TO AGAIN EXPRESS OUR IMMENSE THANKS TO BD FOR SUPPORTING THIS JOURNAL IN 2017 AND, I AM DELIGHTED TO ANNOUNCE, AGREEING TO CONTINUE THIS INVALUABLE SUPPORT THROUGHOUT 2018 FOR ANOTHER SERIES OF FOUR EDITIONS.**

*So why not order a Quattro Stagioni pizza to eat whilst you enjoy this fourth edition of MDET. Happy reading. Fire up the Quattro .....*

# Home trainer

Six weeks in hospital, or learn to administer your own drugs and go home instead? Many patients on intravenous antibiotics are increasingly choosing the latter option, thanks to innovative programmes in which healthcare professionals teach how to self-administer IV drugs. Instructing a non-clinician might involve some unique challenges but, as Claire Read discovers, success means benefits all around.



You've been feeling ill for a while. High temperature. A red, swollen leg. And a lot of pain. But there's good news: the doctor knows what's wrong. The tests have shown you've got an infection in your bone. It's easily treatable with a course of antibiotics.

**Thing is, though, the course is going to have to last several weeks and the drugs be given directly into a vein. And you're going to have to stay in hospital throughout.**

As a consultant in infectious diseases, and with a special interest in bone and joint infection, this is a conversation Dr Emma Nickerson was used to having.

The reality is that, often, she could tell a patient that after a week or 10 days of treatment with intravenous antibiotics (IV) they would be well enough to go home.

But the course needs to continue every day for six weeks, either on an outpatient basis or with district nurses visiting the patient at home to give the medication. And for many patients at Addenbrooke's Hospital in Cambridge, neither was an option.

*"We're the regional trauma centre, so our cases often come from much wider than our local catchment area," explains Emma. "If a patient lives a lot further away [from the hospital], then it would be totally impossible to attend every day.*

*"And it tends to be pot luck whether you live somewhere where there are district nurses who are trained to do it," she adds. "In some areas, it depends on the GP practice you're registered with, but [even if it is offered] often the district nurses can only come once a day. So if a patient happens to have an infection that requires an antibiotic more than once a day, then that becomes a no go."*

Traditionally, that meant for many patients there was no option but an admission for the whole course of their treatment. It was a solution which wasn't great for Addenbrooke's - "we're the same as any other hospital, there's massive pressure on beds and access" - or for patients, who were stuck in a hospital bed despite possibly having no medical need for it.

So in recent years, there has been another choice on the table for patients: learning how to administer their own IV antibiotics. Emma admits many are surprised when they hear it's a possibility.

*"There's very much: 'I've never done anything like this', or 'I'm not medical', something along those lines. So one of the things we do is reassure them that actually we teach hundreds of people to do it, so it's not that we're asking them to do something out of the ordinary."*

Emma's trust isn't the only one to have introduced a self-administration aspect to their outpatient parenteral antimicrobial therapy (OPAT) services. At Brighton and Sussex University Hospital NHS Trust, IV clinical nurse specialist and OPAT lead nurse Lucy Francis has also taught many patients how to administer their own IV antibiotics.

*"We had patients waiting and finishing their treatment in hospital for four weeks for once a day antibiotics," she reports. "But they couldn't go home because there were no community nurses. And we suddenly thought, well, why not teach them if we can?"*

She says the teaching involves a few key elements. "They need to learn aseptic non-touch technique," explains Lucy. "That's fundamental. We give them a bit of background about their drugs and how they need to give them. And they also need to know how to care for and maintain their line [a catheter inserted into a vein, through which the antibiotics are given]. And they need to understand complications that may arise either from their medication or from the lines."

**"It's ensuring that they've got a sterile technique, so that they don't give themselves another infection, and that they get the air bubbles out of the syringe," agrees Emma.**

*"One dangerous thing is obviously to inject yourself with air. So those are the two critical things - really good sterile technique, and that they're good at getting the bubbles out and making sure it's safe and are getting the air bubbles out once it's mixed up."*

While Lucy says she and her colleagues didn't need to receive any formal training to instruct people on self-administration - "we are IV nurses, and it's just about IV therapy and how to give antibiotics safely" - she says teaching patients is a little different from teaching fellow clinicians.

*"It's a different ball game. Because we can get carried away with our language and go very technical on them and use lots*

*of jargon, and it's about being aware who you are teaching and what they will and won't understand. You have to adjust the language when you're talking to patients, what do they understand, what do they get from this. It's just different."*

She says it's also been necessary to ensure that all nurses are teaching in the same way. "What we have done to standardise the care and make sure we are teaching the same to the patients is we have written a competency. We've competencies so we are doing everything the same way."

*"So my colleagues wouldn't do it any differently from me, but we have sometimes to adjust to the patient - for their dexterity, or how they understand and how they want to do things, as long as aseptic non-touch technique is met and they are safe in their practice."*

Ensuring consistency has been a focus at Addenbrooke's too. "It turned out, in the early days, that people were being taught very differently - everybody has their own slight variations," reports Emma. "So we had a leaflet to try and make it consistent, and also created videos demonstrating exactly the same technique, so we've got that consistency."

There are eight videos in all, specific to a particular drug (Ceftriaxone, Daptomycin, Tazocin, Teicoplanin, Ertapenem and the three different strengths of Meropenem). The trust has posted them on video hosting site Vimeo, to make sure they're easily available to patients as well as to fellow healthcare professionals.

*"A few patients have said they run the video while they're doing it themselves, so they've got that reminder. Or if they can't quite remember something, they can use it as a refresher. So it's kind of a comfort blanket once they're out of hospital."*

The teaching protocol at Addenbrooke's involves patients watching, doing, and then being assessed. "They watch one dose being done, they have to do three themselves, and then they get assessed," explains Emma. "The teaching is mostly done on the ward, and then the assessment is done by our OPAT specialist nurse, partly because it helps that it's somebody different, and then also it is a consistent standard."

Doctors at the trust try to get all IV antibiotic patients onto a drug which requires only one dose a day. "It's much more convenient for patients," explains Emma. But that means there's only one learning opportunity a day, "and so this process of having to watch one, do three, and be assessed takes five days. And that might prolong the length of stay, which is not what we're aiming to do".

**"What we have done to standardise the care and make sure we are teaching the same to the patients is we have written a competency."**



“It’s saved so many bed days and a vast amount of money.”

Enter the plastic arm. “We’ve got a practice demonstration arm that’s got an IV line in. It’s exactly the same as what the patient would have, all set up the same, and then they can practise on that.

*“By using the plastic arm, the OPAT nurses can take a patient through it very carefully. And lots of patients said they found it really reassuring to do it on a plastic arm before they did it on themselves, particularly for those who are more nervous. And for some people who did not take to this naturally – having a much more intense and lengthy teaching session with someone really experienced, such as one of the OPAT nurses, that really helped people who might not have quite otherwise learnt to do it; that sometimes meant that actually they did get there. And that helped speed the process up as well.”*

If there is any doubt about a patient’s ability to safely administer the drugs, then staff do not pass them to do so. “And without our documentation that they’ve passed and we’re overseeing their antibiotics, pharmacy won’t distribute the drugs. So we’ve got that safeguard.”

But Emma emphasises that there’s plenty of incentives for patients to learn. “They are going to be independent, not in hospital but at home, and not having to wait around for a district nurse. With nurses, there’s usually a two or three hour window patients are given [in which the nurse will visit], so they have to wait in for quite a lot of the day. So they get much more freedom if they learn to do it themselves.”

There are huge benefits for the trust too. “It’s saved so many bed days and a vast amount of money,” reports Emma. “We saved on average 420 bed days a month. So really a lot. And there’s all the costs related to saving those bed days, but then in terms of saving the nurse administration – once a day administration is about £100 a day, and then it’s probably about £70 for subsequent visits. So you’re looking at £42,000 a month just on the nursing what it would have cost to do it in the community. That’s just for once a day, let alone more. So really big sums of money.”

Encouraging patients to self-administer IV antibiotics is also helping healthcare professionals in their desire to empower the people for whom they care. “What I have liked most about it is the patients’ independence, and they tend to learn more,” says Lucy.

*“They pay attention to what they’re suffering from, they pay attention to their medication, they become experts in those other aspects. And they change some things. Like I had a patient with diabetes we were treating for osteomyelitis [bone infection], and suddenly they said: ‘I’m going to change what I eat, because now I understand about my illness more.’ It was quite something.”*

Emma reports something similar. “We’ve certainly had patients who’ve come back and seen a nurse administering something else and said there’s too many bubbles,” she laughs. “Because they’re so highly attuned to what should be done.”

She adds: “Hospitals generally are very disempowering. So this is definitely empowering the patients – they are taking the lead on their own care.”

# On the record

The Care Quality Commission (CQC), Medicine Healthcare products Regulatory Agency (MHRA) and the tenets of the Health and Safety at Work Act all require healthcare organisations to keep detailed records of which staff are qualified to operate which medical devices. But, as Claire Read reports, it's a requirement that is simpler in theory than in practice.

Sam Gilmore is the clinical device trainer at Luton and Dunstable NHS Foundation Trust, but at times a more accurate job title might be spreadsheet guru.

As part of trying to keep an up-to-date record of which staff have been trained on which devices - as required by, among others, the Care Quality Commission - Sam juggles no less than 62 Excel documents.

*"We design them, we keep them, we maintain them, and then every couple of months we send them to the ward managers and the matrons," she explains. "We ask if there have been any staff changes, say this is your staff's current competency, and from that which device training we would encourage them to attend."*

It's a big and important job, but she is aware the result is imperfect. The spreadsheets don't link to the electronic staff record (ESR), so don't always reflect the current staffing.

Sandra Hearn knows this pain all too well. As a medical device trainer at Portsmouth Hospitals NHS Trust, she is also grappling with the challenge of how to keep an accurate database of medical device competencies and training needs for thousands of staff.

*"In our trust, there are only two medical device trainers and we've got 3,000-4,000 staff to train, mostly nurses and associated healthcare practitioners," explains Sandra.*

To make those numbers more manageable, she and her colleague operate on a two year cycle for each clinical service centre - "so, for example, medicine, surgery and so on".

She continues: *"We produce a competency checklist based on the standard equipment we train on, and ask people to sign off as competent on those, or we deliver the training to get them to being competent."*



The idea is then that all this information is recorded in the ESR. But there's a problem. *"It's very hard to pull reports, because you can put somebody down as competent but you can't put somebody down as not requiring the competency."*

*"So if they're shown as not competent, actually they may not be competent because they don't actually require that competency - they might be a support worker that doesn't do infusions, as a prime example. So a snapshot today of how many people in surgery are competent on such and such a pump may not be accurate."*

**"That's really frustrating, because in theory that should be the most up-to-date staffing list, because it's the ESR."**

Just like Sam, Sandra has been driven to Excel. *"What my colleague Vicky and I do - we're the two trainers - when we're running each of these specific area projects is create a spreadsheet."*

*"It has all of the current staff names that we're furnished with from the ward, and then we will fill in this spreadsheet as we go through getting the individual's forms back. That helps us with the training needs analysis at the time, and then obviously we can pull a percentage from that [of the number of trained people]."*

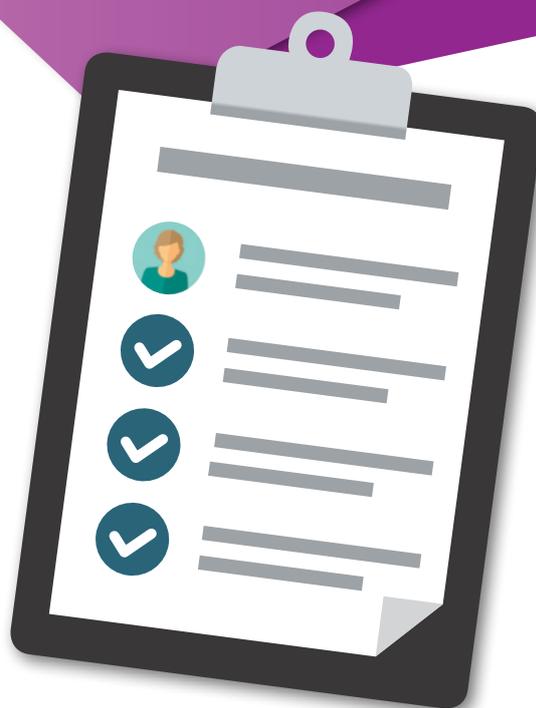
But, she emphasises, those spreadsheets are by their very nature only accurate during the course of the check on that specific area - which represents a four to six week project.

*"In the meantime, people are obviously coming, going. So I'm doing a medical area at the moment and they're at about 81%, which in the state of play of where we're at is very good. But that wouldn't be correct to look at that in December, because a number of staff may have left, moved to another ward. So it's never very tight and accurate."*

It's also an awful lot of work. *"It's time consuming,"* says Sandra. *"We'd rather be out doing the training than this work."*

When Sandra and Sam posted on the NAMDET website asking if anyone had a better solution to the problem, the result was a lively thread. Some talked of using their medical device database to record training. e-Quip offers this as an option, and Sandra is now planning to investigate whether it might be possible to use at her trust.

Others are buying in solutions specifically targeted to keeping medical device training records. A couple of years back, Leeds Teaching Hospitals NHS Trust became the first organisation in the UK to make use of a software package called Melvis. A visit to Leeds by the team at Barts Health NHS Trust means it will also now be implemented in their organisation.



In building the business case for investment, Mary says there was a focus on how the software would improve assurance at the organisation.

*"I have to be able to let my trust board be aware that we have x number of staff requiring x number of training episodes. And if you don't have that information, they [the board] are then unable to work with HR to give training time, or to give us resources to make sure the training is there."*

The new system should also resolve an issue with the trust's current solution, which is a database built in Microsoft Access. *"On Melvis, we'll be able to give permissions for more managers to use it and put their own training on the system. At the moment, managers can look at the Access database but not touch it, because it's not very stable."*

**"On the new system, they will be able to set up their own training requirements and sessions, and if the person is then deemed competent to use that device at the end of it, they will then go and update Melvis directly."**

Beyond that, it is anticipated the new system will essentially deliver the same sort of functionality as the existing database - but in a much more stable format. It will be possible to pull off individual reports, showing the devices in which a specific staff member needs to be competent and when training is due.

Users will also be able to create reports for specific areas of the trust. *"So at management meetings, people can sit down and say: 'Well, on Ward 4A they're all compliant on this, but why on Ward 4B are they not? Or if there's a clinical incident involving a piece of equipment, immediately we can pull off training records.'"*



Some 200 miles north of Barts, at Calderdale and Huddersfield NHS Foundation Trust, staff say they have a system which also allows that sort of analysis.

*"We've got our database to link in with reports of incidents where we believe that there is a medical device training element,"* reports Brian Bottomley, the trust's medical device training support officer.

**"So, just for example, if we found that there was a suction incident on a particular ward, we could look at that ward and say, yes, they're down on the training there, we can go in and focus on it.**

*"And if there were several incidents there, then not only would we say have they not had the training, but actually is the training correct - are we not getting the message across, do we need to think about a different delivery form?"*

The link to incident reports is one of many evolutions to the Calderdale and Huddersfield system, which has been built entirely in house. The database has been in place for about seven years, and replaced a previous version which had been built on Access and wasn't quite meeting need.

*"When I came into post, we didn't really know where we were,"* reports Jayne Blakey, the trust's medical device training coordinator. *"So we did an audit, and from there I realised we needed more. Which is when we then worked with IT to develop this new database."*

Brian says accessibility was a key focus. *"There was a push within the trust for us to use the trust learning system,"* he says. *"But that restricted us to about three or four people who could input the data, so the workflows were impossible."*

## Maintaining training records for medical devices: the main options

From our research, MDET has identified three main options for reliably recording medical equipment training requirements.

**1) An in house database.** *"We've got a fantastic database which has developed and grown as we've developed and grown,"* reports Jayne Blakey, medical devices training coordinator at Calderdale and Huddersfield NHS Foundation Trust. *"If we decide there's something else we need, or a different report or there's a different requirement, then the colleague who built the database builds it in for us."*

**2) Dedicated software purchased from an external supplier.** At present, this is likely to be synonymous with Melvis. *"If you get to the options section of a business case for something like this, there's very little else out there that's bespoke,"* reports Mary Caddies, lead medical devices trainer at Barts Health NHS Trust. *"I really didn't find anything else that came anywhere near what I'd seen [with Melvis] at Leeds."*

**3) Add ons to existing software setups.** We heard from people who were using e-rostering systems to record competencies, and others who were using 'add ons' to their device management database.

*"So we steered very hard away from that. It now means that Jayne and myself actually have very little inputting to do. We still have the organisational stuff to do, but the actual day-to-day inputting is done by managers or trainers."*

Jayne says there has also been a push to put training data onto the ESR, *"but it cannot cope with the amount of information. So now we're developing a link with ESR, where it will basically do a data dump of information onto our system - leavers, new starters, anything like that. We're just developing it and tweaking it so it'll work the way we want it to work."*

At Barts, Mary is one of many who told us they'd like to see a national system in place to manage all of the complexities around keeping accurate training records.

*"I'd love to see it standardised and nationalised, because then if you've got staff transferring from one hospital to another, working on a specific device, then we all know who can do what, where and when. And if there are local requirements, they can also be factored in when you get a new member of staff."*

For now, it seems likely that individual organisations will need to continue with individual arrangements. But if you're currently managing reams of Excel spreadsheets, be reassured that you are far from alone - and that colleagues out there may be able to help you explore other solutions. Sam at Luton and Dunstable has already spoken to the team at Barts and to a local software development company to explore whether they might be able to build a solution.

**"My own experience, and also the responses from NAMDET, have highlighted that there's a huge gap in the market,"** she concludes.

# Getting nutrition right for newborns

**Administered correctly, total parenteral nutrition (TPN) can be lifesaving for premature and seriously ill babies. By giving liquid food directly into the bloodstream, it's possible for a baby who is too small to suckle or too sick to receive milk feeds to get the nutrition he or she needs. But infuse the food too quickly, and TPN moves from life saving to potentially life ending. A new patient safety alert from NHS Improvement makes clear the risks and, as Claire Read reports, suggests training could be a key part of reducing them.**

Maisie Waters was only seven days old when she died. She'd come into the world on 16 August 2011, born by a planned caesarean section and with a problem with her heart. Doctors were confident the problem could be fixed with surgery, and so she was transferred to the paediatric intensive care unit. But she died before an operation could take place, not because of her condition, but because she was accidentally given a day's worth of food intravenously over the course of just one hour.

Total parenteral nutrition (TPN) - in which an individual is fed entirely intravenously - is an important method of helping babies who are unwell or who have arrived prematurely. Through separate infusions of aqueous fluids (amino acids and glucose) and lipids (fats), a patient can receive the nourishment they need - even if they are too small to suckle or have an intestinal problem which means they can't take milk feeds.

Unfortunately, however, Maisie's story is not the only instance in which youngsters have been harmed due to problems with the administration of TPN. As recently as last October, a coroner found that "a failure to ensure correct administration of the TPN resulting in its over-infusion" had contributed to the death of a premature baby at Queen Charlotte's and Chelsea Hospital in London.

And when NHS Improvement recently reviewed the evidence from the National Reporting and Learning System, it found a large number of reported patient safety issues relating to the use of TPN in babies. In a recent three and a half year period, 10 incidents were identified where infusion of TPN at the wrong rate led to "severe harm to babies through pulmonary collapse, intraventricular haemorrhage or organ damage, and where intensive intervention and treatment were needed".

The body reviewed low harm and no harm reports as well, which suggested there had been 700 similar incidents where a mistake had been made with TPN but in which - fortunately - there had been little or no resulting harm to a patient.

The evidence is such that, in late September, NHS Improvement issued an official patient safety alert on the subject. As a spokesperson for the organisation told MDET: "Providing high quality care to patients is our top priority and ensuring that the NHS is able to learn from mistakes to improve future care is vital."



*"We know providers across the country who are treating babies are dedicated to getting that care right. However, in the previous three and a half years there have been instances of harm that potentially could have been avoidable."*

**"THIS PATIENT SAFETY ALERT HIGHLIGHTS THE ACTION TRUSTS NEED TO TAKE NOW TO ENSURE BABIES RECEIVE THIS TYPE OF CARE SAFELY."**

Classification: Official

**NHS Improvement**

**Patient Safety Alert**

**Risk of severe harm and death from infusing total parenteral nutrition too rapidly in babies**

27 September 2017

Alert reference number: MDET/PSA2017/0068

Warning alert

**What:** All organisations providing NHS funded care to neonates and children (especially those under 30 kg) and where TPN is administered.

**Why:** To commence immediately and be completed no later than 6 November 2017.

**What:** To identify if this is used in your neonatal and paediatric departments.

**What:** Bring this alert to the attention of those with a leadership role in the planning and administration of TPN in neonatal and paediatric settings.

**Consider if immediate action is required:** Consider if immediate action is required to ensure that an action plan is in place to reduce the risk of harm to babies through TPN administration.

**Communicate the key messages:** Communicate the key messages in this alert for neonatal and paediatric settings.

**Sharing resources and examples of work:** If there are any resources or examples of work developed in relation to the alert you think should be shared to others, please share them with us by emailing [psa@nhs.uk](mailto:psa@nhs.uk).

**Project summary:** This page lists the technical notes, stakeholder engagement and other information that should be directed to.

That includes making sure training and competency assessments are up to date. Two of the main types of error which NHS Improvement identified in its review of TPN incident reports related to general infusion pump issues - one the incorrect infusion rate having been entered into the administration pump, and two a miscalculation of the correct volumes when fluid or pump-related changes were made. Medical device trainers who are seeking to address

these might well choose to focus on general training around the use of pumps.

But there was also a common total parenteral nutrition-specific error identified by NHS Improvement's reviews of incident reports. In administering TPN, two administration sets and two pumps are required. One set and pump is used to give the aqueous component of the feed, and the other to give the lipid component. Each component needs to be given at a different rate.

In many incidents reviewed by NHS Improvement, the administration set which had been primed with the lipid component was threaded through the pump intended

for the aqueous component, and the set primed with the aqueous fluid threaded through the pump meant for the lipid component. That meant the aqueous was infused at the lipid rate, and the lipid at the aqueous rate.

Ensuring that training in TPN addresses this potential issue could well be a valuable way of reducing the risk of future incidents. The sad cases of Maisie Waters and others make patently clear the harm that can result when things go wrong – and why it's so important staff are confident and careful when they administer TPN.

<https://improvement.nhs.uk/news-alerts/infusing-total-parenteral-nutrition-too-rapidly-in-babies/>

## Actioning NHS Improvement's patient safety alert on total parenteral nutrition in babies

NHS Improvement issued its alert on the risk of severe harm and death from infusing total parenteral nutrition (TPN) too rapidly in babies on 27 September 2017. It applies to all organisations which provide NHS-funded care to neonates and children and where TPN is administered.

The alert instructs organisations to immediately start work on addressing the actions it details, and says such work should have been completed by 8 November 2017.

The actions are to:

- Identify whether TPN is used in your neonatal and paediatric departments

- Bring the alert to the attention of anyone with a leadership role in the prescribing and administration of TPN to babies and children
- Consider whether immediate action is required locally, and institute an action plan to reduce the risk of harm to babies through the administration of TPN. The alert notes training and competency assessments may have a role in reducing the risk of incidents involving TPN.
- Communicate the key messages in the alert – and the plan to reduce the risks – to all relevant staff in the organisation

## TOPLINE SYSTEMS

### IT support services for small organisations, departments and projects

#### Database

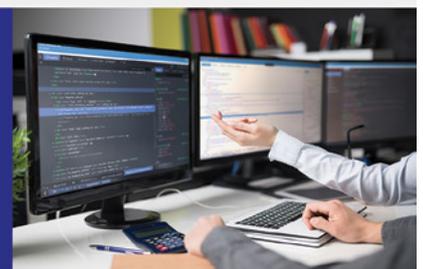
#### Website development

#### Consultancy

- **Development, implementation, ongoing support and maintenance, for new projects and takeover of existing projects**
- **Hosted services infrastructure to facilitate a wide range of services including website hosting, storage, database & telephony services**
- **Our hosted/cloud services are operated from secure UK data centres in geographically diverse locations for increased resilience**
- **Projects team with diverse skills set and 25 year history of providing support and solutions**
- **In-house developers for database and website 'back-end' coding**

```
if ($ENV{'REQUEST_METHOD'} eq  
elseif ($ENV{'REQUEST_METHOD'} eq  
{sysread(STDIN, $form, 8192);  
$form=~tr/+// ;  
$form=~s/%(..)/pack ("C", hex $1, $2)/e;  
$form=~tr/,// ;  
@pairs=split(/&/, $form);  
foreach $pair (@pairs) {  
($key, $value)=split(/=/, $pair;  
$FORM{$key}=$value;
```

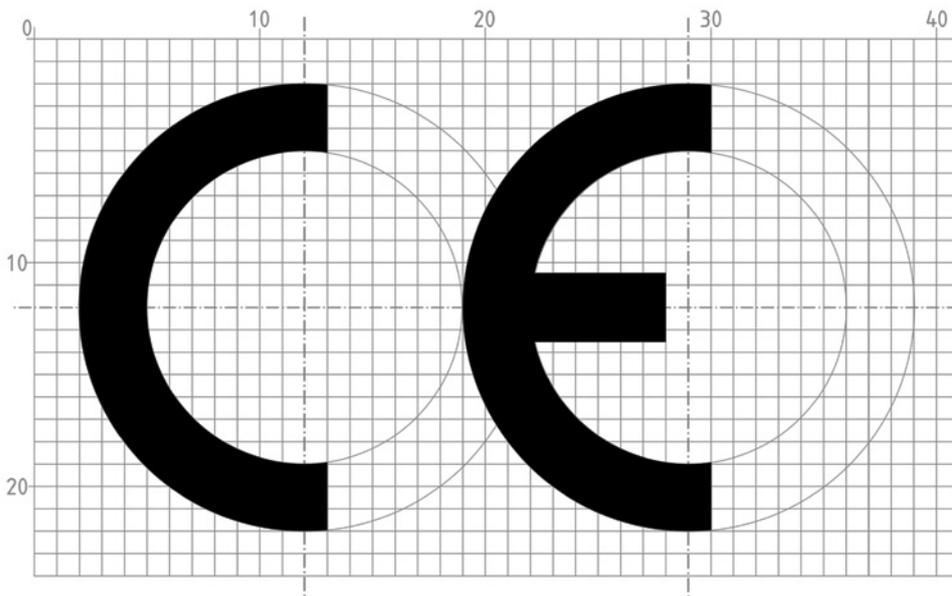
[www.topline.co.uk](http://www.topline.co.uk)  
Projects team: 0121 702 1579  
[enquiries@topline.co.uk](mailto:enquiries@topline.co.uk)





# “Why do medical devices have a CE mark?”

The **Conformité Européenne** or “CE marking” has existed in its current form since 1985. It is a marking that you may have come across on various types of products sold in the European Economic Area (EEA), for example, on children’s toys or home appliances such as hot-water boilers, fridges, and freezers. But what does the CE marking actually mean and why is it crucial that medical devices clearly display this marking?



For many products in the EEA the CE marking is a mandatory certification mark, which indicates that the product has been checked to ensure it meets EU safety, health or environmental requirements. The marking not only indicates that the product is compliant with EU legislation but that it may also freely move throughout the European market without having to undergo additional national conformity assessments. By placing a CE mark on a product the manufacturer, or their European counterpart if the manufacturer is located outside of the EU, solely declares that their product meets all of the legal requirements to achieve a CE marking thereby enabling the product to be sold in the EEA. The CE marking also helps to assure end-users that the product has undergone the appropriate conformity assessments and is backed by the relevant technical files and any supporting other documentation.

It should come as no surprise that medical devices must have a CE marking to assist in demonstrating a high level of protection of health for patients and users. Although there are certain circumstances where a manufacturer of medical devices may “self-certify” that their devices meet the CE standard, in most cases, due to the high standards of quality and safety demanded by EU legislation, the CE certification process must be undertaken together with a Notified Body within the member state where the manufacturer is applying for a CE mark. In the context of medical devices in the UK, Notified Bodies are entities that have been accredited by the Medicines & Healthcare products Regulatory Agency (MHRA). But being granted a CE marking by a Notified Body is not the be-all-and-end-all for medical devices. In addition to obtaining a CE marking, the manufacturer will need to continue to support their devices throughout their life cycle

and ensure that, for example, the appropriate quality assurance systems, clinical evaluations, risk assessments, post-market clinical follow-ups, traceability and vigilance requirements are met and, where necessary, make modifications to the device or facilitate recalls or replacements in line with post-market surveillance. The adoption of the new Medical Devices Regulation in 2017 has also set in motion a race for medical device companies to ensure that upcoming, current and legacy medical devices (still sold in the EEA) will be compliant prior to full implementation of the new regulation in 2020. The new regulation also aims, amongst other things, to improve the quality, reliability, and safety of medical devices in the EEA and to respond to new and emerging medical technologies and techniques including, for example, bringing certain medical software and apps within the scope of CE marking.

The importance of CE marking cannot be understated. It is illegal to sell a medical device in the EEA without a CE marking regardless of where it is manufactured. That said, a CE marking is not a declaration that the device is safe – rather that the device meets all of the appropriate provisions of the relevant European legislation with respect to safety, performance, specification and that it has been assessed in accordance with those standards. It is, therefore, important that hospitals that use medical devices do so in accordance with the manufacturer’s instructions and with the relevant training – a CE marking only covers the specific use(s) identified for that medical device and the upcoming Medical Devices Regulation continues this march towards increased patient safety and transparency. The CE marking also plays a pivotal role in ensuring the compliance of the medical device once it is in the market by making the manufacturer, or their European representative, legally liable for defective medical devices and the legislation includes both civil and criminal sanctions against the business and key individuals.

# Dose-error reduction software (DERS) experience at the Royal Brompton and Harefield NHS Foundation Trust

## Intravenous medication challenges and errors

The WHO third Global Patient Safety Challenge on Medication Safety aims to reduce the level of severe, avoidable harm related to medications globally by 50% over 5 years.<sup>1</sup>

At the Royal Brompton and Harefield NHS Foundation Trust (RBHT), 220,000 IV sets are purchased each year by the Trust, and at least 700 doses of IV medication are administered each week on ICU alone. Two and a half million doses of medication are given every year in the average UK hospital: 10% are administered IV: 86% of these have the possibility for error, so there are around 215,000 potential IV errors per hospital annually.<sup>2</sup> IV medication errors, therefore, have considerable implications to patient safety, efficiency of care and stretched resources.<sup>3</sup>

Stephen Squire, Clinical Engineering Services Manager, RBHT, who has been closely involved with dose-error reduction software (DERS) since its introduction to RBHT in 2004, notes "There are around 2,000 pumps in the average Trust, costing £1-3k per pump. This is a significant financial commitment, and DERS helps reduce IV medication dosing errors; why are Trusts not making their use mandatory?" Mr Squire notes that, in most Trusts, infusion pump and syringe driver errors are in the top three classified medical device errors.<sup>4</sup> At RBHT, they are not even in the top ten. Mr Squire believes it is due in part to the rigorous use of DERS in Critical Care: "We now have a standardised pump fleet which is well-maintained, with a sufficient number of pumps to meet our needs, with an up-to-date drug library. Put that with our electronic prescribing system, and this all contributes to our low error rate."

He continued: "Unfortunately, at the present time, unless a major incident becomes the driver, there is no mandated requirement to introduce DERS, no clear mechanism for its introduction, and no financial incentives." This may soon change as CQC now has increased its focus on the prevention of medication errors, according to Edward Baker, Deputy Chief Inspector of Hospitals, CQC, at The Patient Safety Congress in Manchester in July 2017.<sup>5</sup>

Chris Remington, Specialist Pharmacist - Critical Care, RBHT, since late 2016, has taken ownership of smart pumps and drug libraries. Mr Remington notes "From a Governance, patient safety and workload efficacy perspective, DERS should be used for all IV infusion administrations throughout the hospital setting. IV medication errors can result in a prolonged hospital stay and the need to use additional medications to counteract the effect of the errors. We should avoid this by using DERS."

Why are Trusts not making the use of smart pump technology and DERS mandatory?



"IV medication errors can result in a prolonged hospital stay, and the need to use additional medications to counteract the effect of the errors. We should avoid this by using DERS."

### Box 1. Top tips to minimise IV medication errors

1. Refer to the standard concentration document 'Medication Concentrations in Adult Critical Care Areas' endorsed by Intensive Care Society and Faculty of Intensive Medicine<sup>6</sup> as a starter for your drug library. Note, paediatric requirements often differ greatly from one Trust to another.
2. Create standard orders for IV medicines on electronic prescribing systems which mirror a standardised drug library, with fewer choices to minimise error.
3. Ensure all staff are trained on the use of smart pumps, drug libraries and infusions; quarterly mandated training days are essential.
4. Document and report all IV medication errors, and identify the impact they have.



## Smart pumps and DERS at the Royal Brompton

Alaris™ smart pumps with DERS software (known as Guardrails™) have been shown to support HCPs in achieving their safety and efficiency priorities by intercepting many IV medication errors, including with high-risk drugs, and reducing costs associated with such errors.<sup>7-9</sup>

DERS was introduced to the Brompton in 2004. In 2011, the 'GateWay' project was initiated to integrate the data. In 2013, the UK's first Limited Commercial Release (LCR) of Alaris™ Communication Engine was agreed between RBHT and BD Infusion Division (formerly CareFusion). This was a reciprocal agreement by which RBHT agreed to work closely with BD to refine the features and capabilities of the Alaris™ Communication Engine Platform to meet their needs in terms of drug library deployment strategies and workflows.

### Challenges to introducing smart pumps with DERS

The introduction of DERS required a multi-disciplinary, internally-driven approach, and this can often be a challenge. Also, it can only be introduced once all teams involved are confident in the safety of DERS and are comfortable changing their method of IV infusion administration. The infrastructure and technology required must be in place, including computer systems and network points. BD supplies a useful checklist to help Trusts in this process.

Addressing why it took several years from the introduction of Alaris™ smart pumps into RBHT to now being used routinely on intensive care wards, Mr Squire noted, *"This is a complex process with many obstacles to overcome and different staff groups to engage. However, when we wanted to standardise the IV medication process to improve patient safety and administration efficiency, our ICU pharmacist championed this process, working closely with the Clinical Engineering department. This close working was essential to the success at RBHT."*

Mr Remington initially found the Alaris™ DERS software design made sense. *"It is really useful that there are hard and soft limits, and that I can input standard drug concentrations into the library. Different pumps have different functionality so it is useful that the settings can be adjusted."* Mr Remington is now updating the IV drug library and completing a volumetric dataset for 60 drugs used in critical care.

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**"CQI data helps to justify what you're doing, and shows that the system is reducing dose errors and avoiding increased length of stay."**

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### Useful features of Alaris™ DERS

Mr Remington has found the Editor software very useful. It allows an institution to define infusion parameters for up to 30 care area set-ups. *"ACE [see below] will streamline this process and speed the updating as you don't need to manually upload each individual pump."*

Mr Remington feels the use of the Continuous Quality Improvement (CQI) Event Reporter feature is currently low due to lack of experience and understanding of its true value. *"CQI data helps to justify what you're doing, and shows that the system is reducing dose errors and avoiding increased length of stay."*

Many Trusts only use DERS with an updated drug library in critical care.<sup>7</sup> Royal Brompton & Harefield NHS Foundation Trust plans to roll out Guardrails™ to other wards where their value will be clear as patients are on high-risk drugs, such as heparin, furosemide and vancomycin, and staff can be less experienced, less familiar with these drugs and very busy.

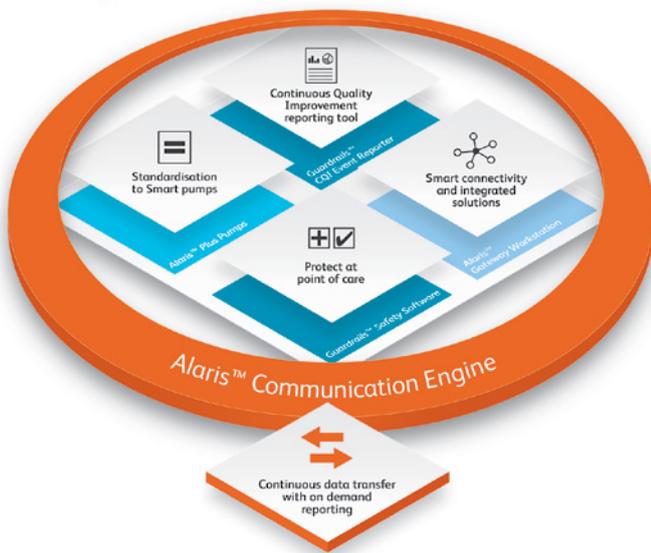
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**Don't only use DERS in critical care; high-risk drugs are used on general wards where staff can be less experienced, less familiar with these drugs and very busy.**

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## Box 2. Top tips to introduce DERS

1. Work closely with Clinical Engineering, Pharmacy, Information Technology, clinical staff and the supplier; don't start the process of implementation without all of these teams on board.
2. Introduce the pumps in a staged process before rolling out more widely; but don't stop at ICU.
3. Agree who will take responsibility for driving the introduction. Pharmacists are ideally placed to take responsibility for the drug library and Clinical Engineering for the smart pumps.
4. Updating the drug library dataset takes time and dedication; it should be done regularly to ensure skills are maintained.
5. Harmonise the datasets in the pump drug library with the electronic prescribing system to simplify connectivity.



## Alaris™ Communication Engine (ACE): enhanced connectivity

Alaris™ Communication Engine (ACE) with Guardrails™ helps to further improve safety, workflow and cost-efficiency. This new communication platform allows drug libraries to be updated, without pumps being located and retrieved from wards. It also enables continuous collection of Guardrails™ data, supporting regular data analysis and improving infusion practice and clinical workflow.

At RBHT, the first upload of datasets via Alaris™ Communication Engine (ACE) with Guardrails™ was in August 2015 as part of the LCR. The first clinically used dataset uploaded via ACE was released in August 2016, preceeded by a test deployment in one pump to reassure members of staff that its implementation didn't adversely affect the other pumps or interrupt other infusions. Since then a further nine datasets have been uploaded. However, the benefits of ACE to RBHT were clear:

- Ability to upload new drug library dataset using software to many pumps at the same time
- More timely uploads of new drugs and dose/concentration changes
- Significant time saving for the Clinical Engineering team
- Significant improvement in asset management

*"With an added feature of ACE that we can now use the network to identify the location of the pump, we can see where the CQI data is generated, and so link it to any observed errors. This is vitally important so we can see where any errors are occurring and address training needs,"* says Mr Squire. Ultimately, BD is working with RBHT to be able to link an error to a particular patient, and include an alert feature in ACE.

The benefits of ACE are acknowledged to be even more significant if it interfaces to the Patient Data Management Systems (PDMS), and BD continues to work closely with RBHT to address long-term connectivity needs.

**The benefits of ACE to RBHT are clear: increased connectivity and data capture.**

## Connectivity in the NHS

Connectivity is the way forward in today's NHS. It will be increasingly imperative that electronic prescribing systems and PDMSs are linked to smart pumps to drive standardisation of care, reduce variation in care, increase patient safety and improve efficiency of care. Mr Remington says *"NHS Trusts have a responsibility to adhere to Patient Safety Alerts (issued by NHS Improvement) for high-risk drugs. Having the connectivity of ACE helps to streamline this process across all pumps within the required timeframe."*

Mr Squire notes *"In the future, the ability to connect data and equipment could help in revenue capture, as well as patient safety."* An example of this is the critical care minimum dataset (CCMDS); activity is often not completely captured and so not all eligible payments are received. If pumps were connected, a more accurate record of doses used would be visible, and so payments could be claimed more easily.

**Connectivity is the way forward in today's NHS. It will be increasingly imperative that electronic prescribing systems and PDMSs are linked to smart pumps.**

### Summary

Intravenous medication errors are a risk for the safety of hospitalised patients. DERS should be used on all wards, in all Trusts, to ensure safe and efficient IV medications management, standardised infusion protocols, reduced unwanted variation, and minimised costs associated with preventable adverse drug events. Alaris™ Guardrails™ Solutions is one of the most comprehensive DERS available in the UK. The new Alaris™ Communication Engine (ACE) enhanced software further advances connectivity and data capture across Trusts.

### Key questions

- What is your IV medication dosing error rate?
- What are the implications of these dosing errors to your Trust?
- Why does your hospital still not use DERS widely?
- Who would champion the use of DERS in your hospital?

### References

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9. Manrique-Rodríguez S, et al. *Int J Med Inform* 2014;83(2):99-105.



**Paul Lee**  
Patient Safety Lead (Medical Devices) NHS Improvement  
(February 17 to September 17)

# The Journey to safer neuraxial connectors in the UK

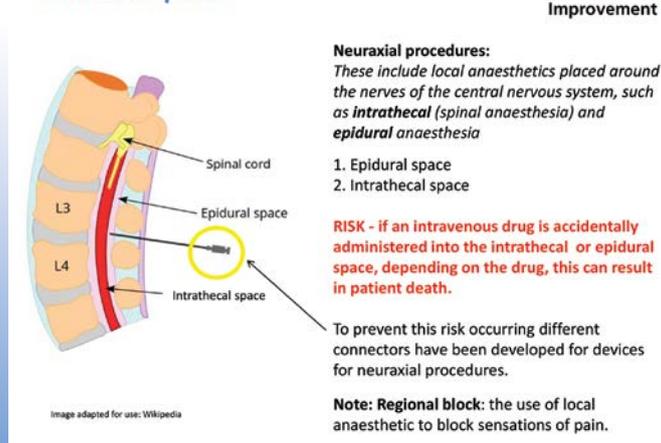
It's been 16 years since Wayne Jowett (aged 18) died in 2001 at a Nottingham Hospital after a frightening catalogue of blunders led to his death. The fatal error occurred when a highly toxic cancer drug (meant to be given through his veins) was accidentally injected into his spinal space on 4 January 2001, causing creeping paralysis and a month's agony for himself and his family, and his ventilator was eventually switched off.

Back in 2001, the connectors used on the end of syringes, needles and adapters for injections and infusions was a universal connector known as a 'Luer' connector. Staff training, procedures and guidelines were used across the UK to help reduce the chance of error, but with all connectors being the same, for all infusions, then this risk of accidental wrong route administration of medication intended for intravenous use via neuraxial route could never be fully removed. This case (which at the time was similar to 13 other cases known to have caused this error) was recorded as a "complex amalgam of human, organisational, technical and social interactions". Prof Liam Donaldson, the Chief Medical Officer at the time, vowed to take steps to prevent another "rare but catastrophic medical error". An independent report later highlighted design faults in syringes and drug packaging.

## Wrong route errors can have fatal consequences.

Clinicians need to inject local anaesthesia around the nerves of the central nervous system into the neuraxial spaces via the Epidural or Intrathecal space.

### Neuraxial spaces



There is a significant risk of harm and fatality when intravenous medication intended for intravenous use is accidentally infused via these neuraxial routes. The Wayne Jowett case, and others before this, has helped drive the change for a safer connector that cannot be connected accidentally to the wrong infusion route, and a new range of safer, dedicated connectors has now been developed internationally.

## The development of a new safer connector for neuraxial procedures.

The basic history of these connectors goes back as far as the late 1800s when a 6% tapered connector was designed for glass bottle stoppers. This tapered stopper was designed by Karl Schneider, working for the firm Hermann Wulffing Luer, which is where the 'Luer' connector gets its name.

### History of connectors

Date	Details	Image
<b>1889:</b> <b>Luer Taper</b> ISO 594:1967 ISO 594:1986 ISO 80369:2016	Luer Taper: 6% taper for glass bottle stoppers Invented by Karl Schneider (Hermann Wulffing Luer) Luer Lok™/Slip™ (Becton & Dickinson)	
<b>2011- 2016</b> <b>Surety®</b>	Bespoke non -Luer connector  One company (Intervene/GBUK Ltd.)  Adopted by many NHS organisations in the UK	
<b>2016 –</b> (ISO 80369-6) Known as; <b>NRFit™</b>	The NRFit™ ISO standard is now appearing across the UK and a full range of devices with NRFit™ connectors expected to be available by April 2018	

In the 1930s a locking version, known as the Luer Lok™, was trademarked by the firm Becton Dickinson (BD) and the two trade names 'Luer Lok™' and 'Luer Slip™' have now become synonymous with syringes and connectors used in healthcare ever since.

The universal Luer connector has been used on a wide range of medical devices in the NHS for decades. This includes intravenous, arterial, blood pressure connectors, breathing systems, neuraxial (i.e. spinal, lumbar puncture, intrathecal drug administration, and epidural) and regional devices such as needles, syringes, filters and tubing.

In 2010, a new international standard for small bore connectors (ISO 80369) was developed and this included a number of different connectors used for a variety of devices in healthcare. One of the connectors is for neuraxial infusions and is known as NRFit™.

Luer (Slip & Lock) In use for decades For intravenous use and Neuraxial use	Surety® 2011 to 2017 Non ISO approved Withdrawn Dec 2017	NRFit™ 2017 - For all neuraxial devices (intrathecal, epidural, regional)
		

However, in 2011, as the international standard was expected to take a number of years to develop, one manufacturer developed an interim safety connector known as Surety® and this has helped to address some of the risks of accidental misconnections of neuraxial devices. This connector was not taken up by all NHS Trusts and is not compliant with the ISO standard, and from December 2017 will no longer be manufactured or imported into the UK. This connector is now being replaced by the new NRFit™ ISO approved connector for neuraxial devices.

## Previous Patient Safety Alerts and Safety Notices.

In recent years there have been three Patient Safety Alerts specifically focused on these neuraxial connectors.

1. In January 2011 the National Patient Safety Agency issued an alert asking NHS Trusts to consider..... safer connectors that cannot connect with intravenous Luer connectors... This helped organisations move towards safer devices for certain high risk procedures.

**Neuraxial connector Patient Safety Alerts**

- NPSA alert January 2011**  
 .... safer connectors that cannot connect with intravenous Luer connector...
- NHS England: Feb 2014 directive alert**  
 ...devices with non-Luer connectors that cannot connect with intravenous devices for intrathecal chemotherapy....
- NHS England: March 2015 warning alert**  
 Identify if medical devices affected by the change are being used in your organisation.  
 If these devices are being used, ensure that an **action plan is underway to minimise the risks during the transition period.**

2. In February 2014, NHS England issued a directive alert ... around 'intrathecal chemotherapy' with a focus on non-Luer connectors that cannot connect with intravenous devices.

3. In March 2015, NHS England issued a warning alert asking NHS Trusts to:

a) identify if medical devices affected by the change to new ISO connectors are being used in their organisation; and

b) If these devices are being used, to ensure that an action plan is underway to minimise the risks during the transition period to the new ISO connectors.

## Where are we now?

Patient safety incidents are still occurring due to the accidental misconnection of an intravenous infusion to a neuraxial device resulting in the patient receiving drugs through the wrong delivery route. As of 2016, the ISO standard now includes a dedicated connector for neuraxial and regional devices known as NRFit™ (ISO 80369-6:2016) which is not compatible with Luer connectors. The new ISO standard has now been adopted by industry for use throughout the UK and the dedicated connector for neuraxial devices, NRFit™ is now available and the initial range of devices now on the market is sufficient for intrathecal procedures (spinal anaesthesia, lumbar puncture and intrathecal drug administration).

In August 2017, NHS Improvement issued a patient safety 'resource' alert to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures,

## Useful resources



**Patient Safety Alert**

Resources to support safe transition to ISO connectors for intrathecal chemotherapy, epidurals and regional blocks

View this alert and check for updates: [improvement.nhs.uk/news-alerts/resources-to-support-safe-transition-to-iso-connectors-for-intrathecal-chemotherapy-epidurals-and-regional-blocks/](https://improvement.nhs.uk/news-alerts/resources-to-support-safe-transition-to-iso-connectors-for-intrathecal-chemotherapy-epidurals-and-regional-blocks/)

### Other useful links:

- Small bore connectors: an introduction to safe use [improvement.nhs.uk/resources/small-bore-connectors-safety-introduction/](https://improvement.nhs.uk/resources/small-bore-connectors-safety-introduction/)
- BAREMA, the Association for Anaesthetic and Respiratory Device Suppliers [www.barema.org.uk/](http://www.barema.org.uk/)

and delivery of regional blocks as NHS trusts plan to move away from both Luer and Surety® connectors for all neuraxial procedures.

This alert was led by the NHS Improvement's 'neuraxial connectors oversight group' with membership comprising NHS Supply Chain, Department of Health Supplies & Resilience, the MHRA, BAREMA and industry. The alert shared additional resources including supporting information for organisations when considering when to transition, as well as a short five minute video to help those implementing the alert understand the terminology and complexity of change required to safely transition to the new, safer neuraxial connectors across the NHS. This alert and supporting information is freely available via the NHS Improvement resources link at the bottom of this article.

It is currently anticipated that a full range of NRFit™ devices required for all intrathecal procedures, epidurals and regional blocks will be available to the NHS by April 2018, but timing is driven by industry and suppliers may have varying timescales for introduction of their products to the market.

The withdrawal of the Surety® devices before a full range of NRFit™ devices is available, creates risks that organisations need to recognise and manage as safely as possible. As this is a major change in the design of equipment, there is a need for a carefully planned transition to ensure staff are prepared. Without effective planning staff may find they are:

- using equipment they are unfamiliar with
- starting a procedure with equipment that is not compatible (i.e. syringe and portal)
- temporarily reverting back to using equipment with the same connector for intravenous and neuraxial administration, posing a safety risk to the patient.

NHS Improvement, Department of Health and NHS Supply Chain are working together with industry to support organisations in their transition to ISO compliant neuraxial connectors (NRFit™).

## The future.

If he survived his treatment, Wayne Jowett, who was training as an apprentice mechanic, would now be 34 years old. The adoption of the safer NRFit™ neuraxial connector, albeit 16 years after his death, and the drive to continue with the ISO standard for the other types of connectors to help reduce risk, harm and ensure patient safety should be seen as one major factor in improving infusion therapy safety. The case highlighted 'design faults in syringes and drug packaging' and the NHS and industry has gone some way towards reducing these risks, but we must never forget the highly complex nature of healthcare and the ongoing vigilance required of our medical and nursing staff to ensure an ever improving safety arena for all our patients.



# THERE IS A LEADER IN ALL OF US -

**NOT EVERY DAY BUT WE ALL HAVE TO LEAD  
ON SOMETHING AT SOME POINT DURING  
OUR CAREER OR LIVES.**

**IT CAN, HOWEVER, SOMETIMES  
BE DIFFICULT TO FIND YOUR OWN  
LEADERSHIP QUALITIES RATHER  
THAN RELY ON OTHERS TO LEAD  
ON YOUR BEHALF. FOLLOWING  
OTHERS IS THE EASY OPTION BUT  
FOLLOWERS ARE ONE STEP AWAY  
FROM BEING LEADERS IN THEIR  
OWN RIGHT.**

In healthcare strong leadership is important in ensuring patients are safe throughout their care pathway and managing different and sometimes challenging personalities within a team can test your leadership abilities. The role you undertake within the team can be a hurdle to providing leadership due to the perceptions of others.

So what inspires you as an individual? Have you had a great leader or mentor in the past that has made you better at what you do? Have you taken from them ideas and ways of working that made you better at leading a team?

If you have you may feel empowered to lead on a project within your department. However, to achieve the outcome you will require a vision of the future - what things will look like

following completion of the project. The vision should be one that motivates and inspires your team members, one that makes them want to engage with you and your vision.

It is important that you know your own strengths and weaknesses to allow you to engage with colleagues that fill the gaps in your knowledge and skill. A good leader will understand their team and know how to adjust their style according to the individuals that you will be leading.

When heading out on your project it is important that the team have a shared mental model, you all know where you are heading and everyone knows clearly and believes strongly in what you have been brought together to achieve. If the purpose is continually at the forefront of their thinking it will underpin their actions and decisions. The purpose is about the mission or goals but also about aligning the team and defining how they will work together. The team must believe they are capable of achieving their goals. So as a leader one of your main priorities will be to ensure you have a team with the correct skills and knowledge to achieve the goal set, but that they know they are capable of achieving it.



At AfPP we support theatre professionals all the way through their career and we are currently running a series of workshops around leadership. The days are, however, suitable for anybody who works in a senior capacity or is working towards a more senior leadership post.

Dawn L Stott  
*Chief Executive, AfPP*

**The next session is being  
held in Wales on Saturday  
7 October 2017.**

There is still time to book your place. However, if you can't make this date we are holding another session in Edinburgh on Saturday 18 November 2017 at the University of Edinburgh.

Please check out our website for details [www.afpp.org.uk/events](http://www.afpp.org.uk/events)

# MHRA delivers guidance on human factors



In collaboration with key stakeholders, MHRA has produced guidance on the human factors aspects of design for medical devices including those in drug-device combination products.

This guidance is intended for manufacturers of all device classes and developers of medical devices and drug-device combination products, and notified bodies to highlight the important influence human factors have on patient safety. The advice is also relevant to device components of drug-device combination products that are regulated as medicines.

Although it seeks to clarify regulatory expectations of medical devices marketed in the UK, the guidance does not represent a compliance requirement.

An engaging multi-disciplinary stakeholder day on human factors and the implications for patient safety led to the formation of the Human Factors Task and Finish group. The group was chaired by Dr Peter Nightingale, who is also the chair of MHRA Devices Expert Advisory Group (DEAC) and Tony Sant, group manager in the Devices Division, MHRA. Membership was drawn from MHRA, academia, industry, NHS Improvement, NICE, notified bodies, professional associations and trade bodies, and the resulting guidance is the collective effort of that group and of feedback from further stakeholder engagement and the public consultation of a first draft published in June 2016.

In simple terms, 'human factors' refers to how a person will interact with the system surrounding them, including the technology they use. Human factors takes into account the environment, user population and potential competing distractions.

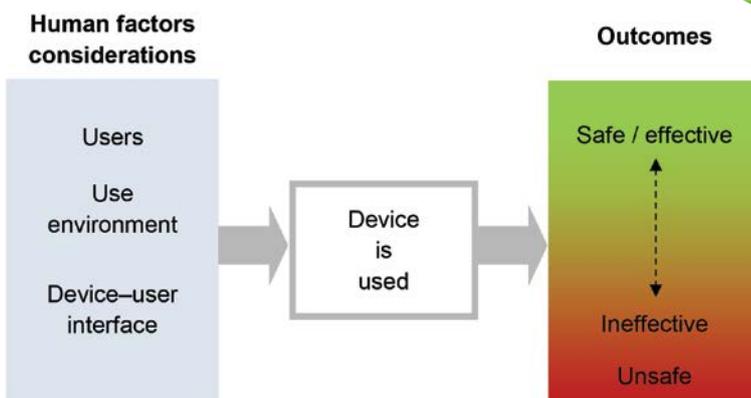
Human factors principles have been applied in high-hazard industries such as defence, nuclear, petrochemical and transport for many years, to minimise the risks from use error and promote safe practices and take advantage of

technology that anticipates and mitigates use errors. In the healthcare sector human factors have become increasingly recognised as an important topic. Following recognition of improvements that were required in healthcare, a concordat from the National Quality Board, published in November 2013 described human factors in healthcare as: 'Enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities and application of that knowledge in clinical settings'.

## Here's why human factors matter for patient safety

A growing number of medical devices are being used for monitoring and treating patients, and errors in use leading to patient harm have been increasingly a cause for concern. Such errors may be due to poor device design, particularly where a complex user interface is involved.

Medical devices, such as infusion pumps, ventilators, automatic electronic defibrillators and drug-device combination products (e.g. auto-injectors) are recognised as potentially having use related design issues that can result in problems such as overdoses, incorrect therapy and dangerous delays or difficulties with delivery of medication. As medical devices become increasingly diverse in their capabilities and the environments in which they are used becomes busier, with new distractions and requirements for specialised training, the potential for use error also increases. Furthermore, as healthcare evolves and patient care is transferred to the home or public environment, less skilled or even unskilled users, including patients and carers, must be able to use quite complex medical devices safely.



**Figure: Human factors affect outcomes of using medical devices**  
Adapted from: FDA's 'Applying Human Factors and Usability Engineering to Medical Devices' guidance February 2016

John Wilkinson, MHRA Devices director, praised the collaborative effort to produce the guidance.

*"Medical devices are becoming ever more complex and diverse, encompassing drug-device combinations and companion diagnostics."*

*"Patient care is increasingly being transferred from hospitals to patient homes and community settings. As these developments occur the potential for use error increases. We recognise this and have collaborated with partners to produce the first UK guidance on human factors."*

**Sue Ferns is Deputy General Secretary of Prospect, the union for professionals representing around 50,000 members working in STEM-based industries across key sectors of the economy and a Trustee of The Science Council.**



Sue Ferns Deputy General Secretary of Prospect

**Science Council**

#### Professional recognition and reward - it makes sense.

I have the privilege to work for Prospect, the trade union representing around 50,000 members in science, technology and engineering (STEM) occupations and proud to be a Science Council Trustee. Right now our members have a lot to be concerned about; not least the implications that Brexit will have for future science funding and research collaboration. Yet, amidst uncertainty, there is one constant: That is the high priority that members place on professional recognition and reward, both for themselves and for those entering into their field of work. Too often it seems that the contribution of scientists and technicians lacks the visibility and status that it deserves.

That is why Prospect was so pleased to be offered the opportunity by the Gatsby Foundation to develop and run a programme to promote the professional registration of science technicians through the Science Council's excellent registers.

Our 'RegTech' programme engaged 22 employers over a two year period. Rachel Bennett, Prospect's RegTech' project manager reports that the partnership with the Science Council and key science employers resulted in a reappraisal of the vital role played by technicians.

Earlier this year Prospect and Diamond Light Source struck a formal agreement to work together to raise the status and registration of technicians across the business. DLS has also introduced a professional registration week each year and meets the costs of professional membership and registration fees for its employees.

In addition Prospect has:

- **Trained 24 RegTech advisers in five organisations as workplace advocates of technician professional registration.**
- **Developed an online training module focusing specifically on the RSciTech register.**
- **Held workplace surgeries and workshops to help technicians with professional registration.**

Prospect's website has resources dedicated to technician professional registration and career development alongside a RegTech advisers network. We also have a responsive careers website - <https://careersmart.org.uk/industries/stem> - focused on providing impartial information and advice.

The Science Council and Gatsby's partnership 'Technicians make it happen' campaign is doing a great job in raising awareness but we need to make it as easy as possible for busy people to engage and to explain how this will benefit their own area of work. That's where organisations like the Science Council can make a real difference by providing support specific to the science registers.

Already 23 science employers have signed up to the Science Council's initiative to champion professional registration at all levels - from technician to chartered scientist and it's having real impact, with applications up by 40% over the last year. But there's still huge untapped potential.

If the UK is to achieve the high skilled, high value added economy it will need for the future, we all need to join together to follow this work through.

Find out more or start your application today at <http://sciencecouncil.org/scientists-science-technicians/>



# What does good training look like!!!

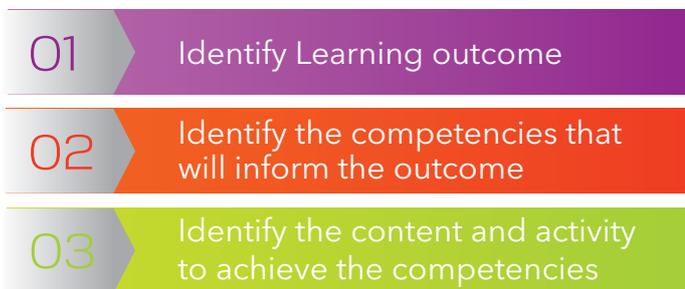
In previous articles, we looked at how to deliver competence based training in four easy steps followed by learning styles/teaching styles. To complete the perfect structure for good training the last piece of the jigsaw is having a plan and deciding on the content you will include. So...

*Identify the learning outcomes for the learner AND identify the learning outcomes for You, the trainer when delivering the session.*

*Once you have identified the learning outcomes and take home message for the learner you need to identify what competencies are needed by the learner to achieve the learning outcome.*

*Once you have identified the competencies this will inform the content for a session or skills workshop e.g. what content do learners need to be able to achieve the competencies.*

## The Plan



Now that you have a plan for content and format, think again about your learner and ask yourself:

Have you developed outcomes expressed from the learner's point of view?  
Or from their frame of reference and /or experience to date?

Do you make it clear to the learners why the specified learning outcomes are necessary?

Have you identified what should be learnt/achieved?

## The Structure

The structure to any teaching session should follow this formula:



In the "set" you clearly state who you are, what your role is going to be, what the outcome will be, why it is relevant or of interest to your learners and how you are going to run the session i.e. small group, formal lecture, lecture plus hands on/bioskills etc....choose the right format for your learning outcomes.

## Four possible outcomes from any teaching session



**Dialogue** - This is where you put the content. In the introduction to your session clearly state the purpose and what your learners will know/have learned by the end. For the information to transfer to your learners you have to achieve engagement. This can be done quickly and easily with use of prepared rhetorical questions and inclusive language e.g. **we** have all seen, **you have all** been asked, **we have all** experienced.....engagement is key. Prepare for the most likely questions, BUT...relax no one knows **everything!** Remember to repeat back questions from the audience and remember- questions during the session rather than at the end make for a more interactive session.

## Do the Maths



**Closure** - Having delivered your content, then take questions from your learners. Allow time for questions during **Closure**. Use 'polite assertiveness' if time is short and deal politely with irrelevant questions; "an interesting question, but outside the scope of this discussion!"

Once all questions are answered, summarise the take home message from your session. When your summary comes after the questions, it is your summary that people remember and not the last question that was asked.

*In summary...*

A good lecturer shows a high level of technical proficiency, commands their environment, **SETs** the scene and flags up the relevance of their session to the learner/audience, engages the audience in a **DIALOGUE**, achieves **CLOSURE** and leaves the audience with a clear take home message.

# NAMDETs

## Hidden Education Jewel -

# The Medical Device Driving Licence

### Introduction

Medical devices continue to play an ever increasing role in modern healthcare and they make a major contribution to the safety, efficacy and efficiency of patient care. Inevitably their use is associated with adverse incidents, mostly minor, but some leading to serious harm to both patients and on occasions the user. There is an increasing body of evidence to suggest that many of these incidents arise from user error rather than from device faults. User education and training is key to the prevention of these adverse incidents.

### So what is MDDL?

MDDL is a series of tailor-made generic device training courses that assists daily routine, and has positive practical implications in the workplace. It will also provide a certificate of proof of completion and competence that users understand the generic device that they have chosen to undertake the training and assessment for. Users would then undertake modular training relevant to the devices they use in their clinical practice and record successful completion of this training as categories in their Medical Device Driving Licence. Where possible such training would be

delivered as part of a national medical device training programme but modules could also be obtained from device manufacturers where appropriate. The MDDL was developed by the Devices Clinical team at the MHRA as a repository for certified training and to help keep all users medical device e-training information in one safe place.

### Medical Device Training

Currently the organisation and delivery of medical device training is hugely variable and no two healthcare organisations adopt a common approach. Training comes from a variety

of sources including a small number of nationally available programmes and locally developed schemes. Where possible, such training should be delivered as part of a national medical device training programme. Whilst much of the current training is excellent, often it is frequently poorly recorded and is seldom transferrable between organisations. The result of this is that many healthcare professionals have to repeat device training when they move between Trusts or other organisations and some escape any formal training at all.

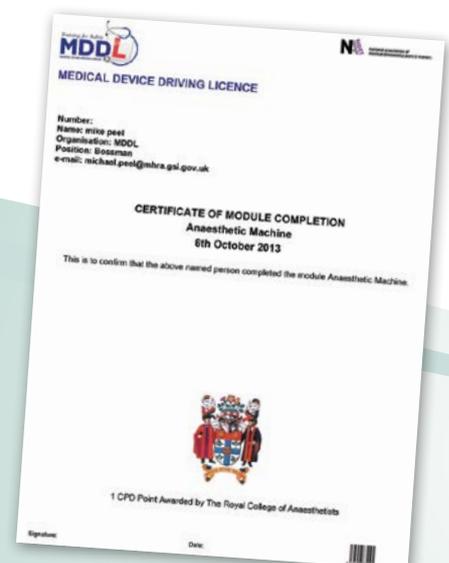
### The Medical Device Driving Licence

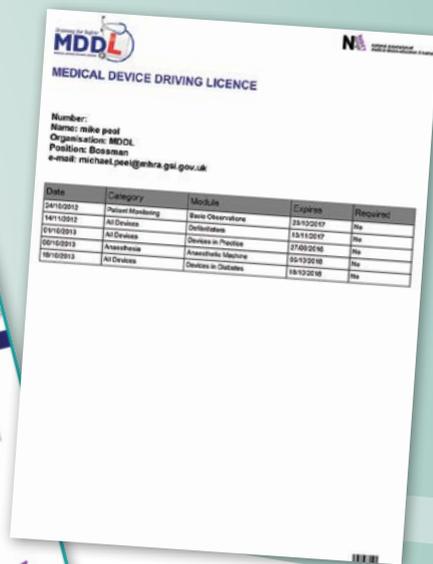
The proposal is to develop a national record of training and competency in the use of medical devices by healthcare professionals. All users would undertake a basic module in the safe use of devices available nationally and delivered electronically through the MDDL portal.

NAMDET has worked closely with the MHRA for many years on a variety of



**Mike Peel**  
MDET Editor





When you have successfully completed an assessment you can choose to download and print a certificate for your personal records.

projects and is actively involved in giving advice, reviewing guidelines and developing national best practice documents. The medical device education modules and MDDL have been gifted to NAMDET in order to be able to support new and already registered MDDL users. NAMDET has plans to work with other developers and enhance the already well established courses and training on the MDDL website.

### Who is MDDL for?

It is aimed at all and any professionals in health and social care

### What modules are available

- Devices In Practice
- Basic Observations
- Defibrillators
- Electrosurgery
- Anaesthetic Machines
- The Operating Table

### How does it work?

The MDDL is a Web based programme in which you log into your own personalised record. Login names and passwords are supplied by email the first time you use the system. When you are logged in you can choose to

undertake assessments on a variety of medical devices. Devices are arranged into simple categories. You may undertake assessments either voluntarily for your own education or because your employer has asked that you do so. Many assessments will expire after a period of time and will need to be repeated so that they remain up to date. When you have successfully completed an assessment you can choose to download and print a certificate for your personal records. The assessment will also be recorded on your own personal "Driving Licence". Again you can download and print a copy of your latest driving licence for your records.

### What do the assessments consist of?

The MDDL will make use of a wide range of different assessments including:

- MCQ questions
- Drag & Drop matching questions
- Sequential step tasks
- Practical Procedural assessments

### Who sets the assessments?

Assessments are written by experts in the use of particular devices from a range of clinical backgrounds.

### Is it successful?

To date over 6000 users have registered and we have issued over 8000 certificates to successful users. The

MDDL Basic Observations and Devices in Practice are the most used modules and many training establishments use these two modules as necessary entry level passes that must be brought to courses as proof before being allowed to progress. Whilst we do have higher level courses, Anaesthetic Module and Electrosurgery which are aimed at surgical staff we would like to find ways of engaging more with doctors and surgeons.

### Where can I get more information?

The MDDL is linked to the NAMDET website but is also available directly at [www.mddl.org.uk](http://www.mddl.org.uk) We have also provided a short presentation on the homepage and full instructions.

### Where next for the MDDL and ELearning

NAMDET has been working closely with Tom Clutton-Brock at Birmingham University Hospital to update and review the current modules and to move toward developing new E-learning training. We are also updating the website and making it easier to navigate. We will update you on progress through these pages in upcoming editions and also on the NAMDET website.

Give it a go.



# SELFIE

## TOM CLUTTON-BROCK

**Age:**

60 years

**University / NHS role and where:**

Reader and Honorary Consultant in Anaesthesia & Intensive Care, University of Birmingham and University Hospitals Birmingham NHS Foundation Trust

**NAMDET role:**

Nothing official, contributor to several conferences, key note speaker 2016

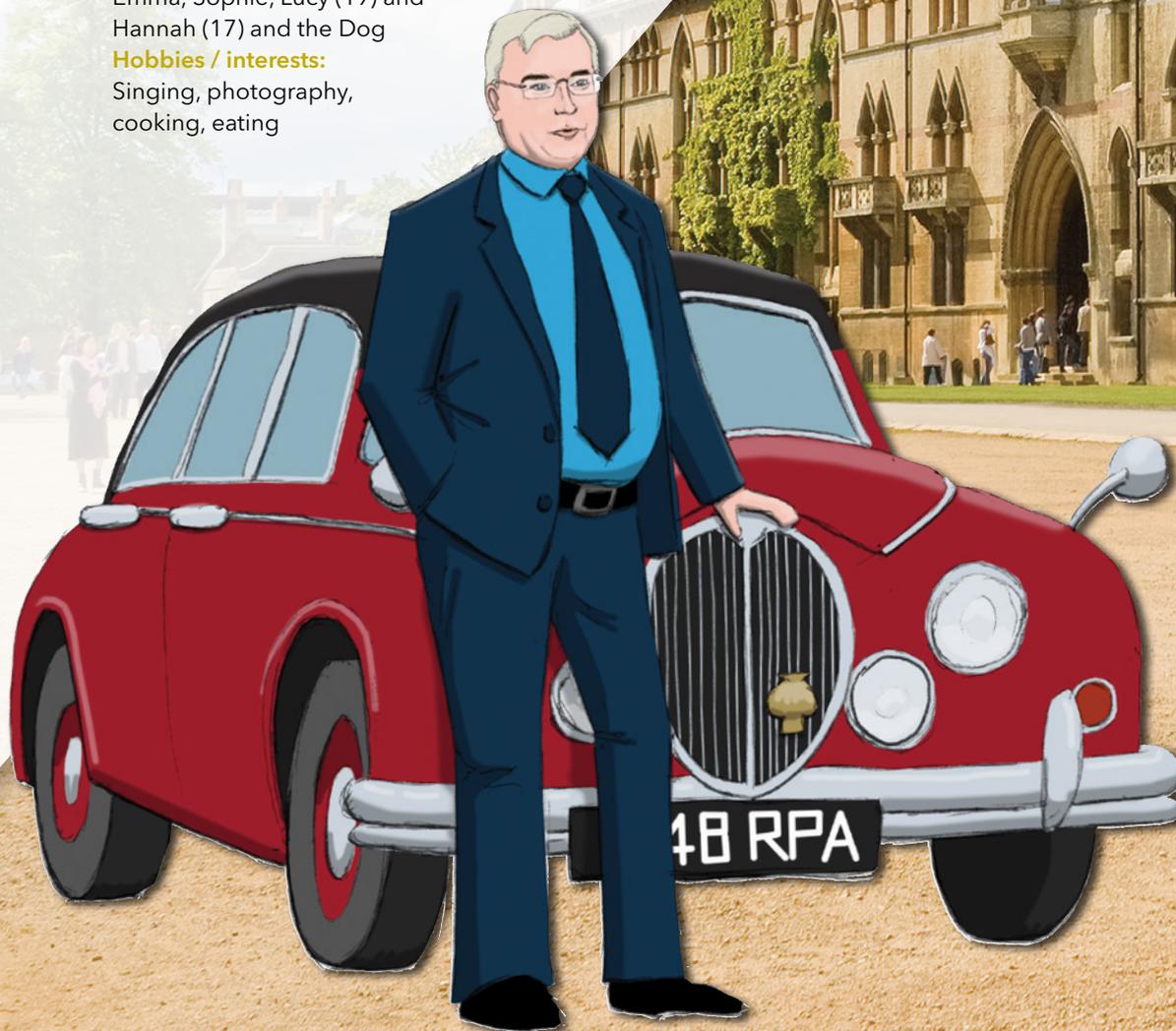
**Family:**

*(names and ages any children):*

Wife-Caroline, 4 Daughters (!) Emma, Sophie, Lucy (19) and Hannah (17) and the Dog

**Hobbies / interests:**

Singing, photography, cooking, eating



**What do you find most challenging in your NHS role?**

End of life discussions with distressed relatives

**What has been your most significant accomplishment in your NHS work?**

37 years of continuous clinical practice, research and teaching success, appointment to chair a national committee at NICE

**What advice would you give those starting the same career path as you today?**

Enjoy it! Develop a varied career

**What thing about your work frustrates you the most?**

Exponential rise in bureaucracy

**What changes would you like to see in the NHS relating to medical devices?**

Much clearer routes to adoption and funding

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

Concentrate on the things you do badly!

**If you could give one message to the Brexit negotiators, what would it be?**

Adopt European Device Regulations without unnecessary UK meddling

**Why do you support NAMDET?**

Great people making a real contribution to patient safety

**In November, NAMDET has their own conference and are also running an educational stream at Patient First. What sessions / speakers at these are you most looking forward to hearing and why?**

All of them

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

Engaging clinicians in device safety

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

Chief Inspector Endeavour Morse

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

CEO of a medical device company (eventually!)

**If you were granted three wishes what would they be?**

2 new knees, a BMI of 24.5, to sing counter tenor professionally

**What's your favourite book or film and why?**

The Kings Speech, my father stammered very badly

**What's your favourite song and why?**

Dove Sei, aria from Handel's Opera Rodelinda, sung by Andreas Scholl, Metropolitan Opera New York, 2012. If you haven't heard it you haven't truly lived!

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

My colleagues, my wife, my children

**We believe from your conference presentation last year that you have invented / built / adapted devices yourself over the years. Which are you most proud of and why?**

M2 Cardiopulmonary Bypass monitor by Spectrum Medical. Step change in bypass monitoring and a great team to work with

# Supporting Serbia

A random conversation led **Steve Logan** to create a charitable initiative to support firefighters in Serbia. Along with colleagues at the South Wales Fire and Rescue service, he started to donate fire engines to replace ageing Serbian ones. But then in the middle of last year he received a request for hospital beds, and a new aspect of the Blazing to Serbia project was born. Claire Read reports.

From the outside, it looked like any other articulated lorry. It was perhaps a bit unusual to see a Serbian lorry in Wales on a November day - or any other day, for that matter. But any bystander would likely have assumed the Nim Šped vehicle from Čačak in western Serbia was transporting something pretty conventional. Products for a supermarket, perhaps.

In fact, it contained 65 disused hospital beds and 10 hospital trolleys, destined for the Balkans as part of a charitable initiative run by local firefighters.

The seeds of that unconventional cargo were sown six months prior, but the project of which it formed part has a much longer history. Its genesis lies in a random conversation Steve Logan had a decade ago.

*"In 2006, I decided to get myself a youth working qualification because I run the young firefighters branch here,"* explains Steve, the commander at Caerphilly Fire Station.

*"On the course with me was a Scout leader, from Caerphilly, who'd recently returned from Serbia with a group of Scouts. Naturally enough, we got into conversation and he said, whilst in Serbia, they'd visited a fire station to find the fire engines were almost 40 years old."*

Steve's new friend asked how often fire engines were replaced in South Wales. The answer at that time: every 15 years.

*"As a result of that conversation, which was September 2006, myself and two other fire fighters from Caerphilly, together with two Scout leaders, then paid for ourselves to go out to Serbia in March 2007,"* remembers Steve.

*"We went out to Serbia and had a look at all aspects of the fire service, from fire stations to vehicles, equipment, uniforms etc, and it was obvious - even on that first visit - that some of the things that we routinely replaced, and literally threw away, they didn't have in Serbia."*

**By the time he returned to Caerphilly, Steve had an idea. Could the South Wales Fire and Rescue Service donate equipment it no longer needed to their compatriots in Eastern Europe?**



*"So I started making a nuisance of myself,"* he jokes, *"with the people sat at the top table in my organisation. And as a result, I secured old vehicles and equipment that were being disposed of - I secured them to go to Serbia. I was providing a secure disposal route for items which otherwise the service would have to pay to dispose of."*

Blazing to Serbia was born. The team has since donated 24 fire engines - 23 to Serbia, and one to a Serbian enclave in Bosnia. *"All the fire engines are fully laden with equipment - breathing*

apparatus, ladders, hydraulic rescue equipment, uniforms and so on," explains Steve.

A while ago, he came across a store of gas-tight suits which the service was planning to dispose of. The suits protect emergency workers from dangerous chemicals, and disposing of them is complicated.

"Of course you can't just put them into landfill," says Steve. "You have to chop them up into nothing bigger than inch and a half squares, and then pay a company to environmentally dispose of them."

**So Steve asked if he could have them. "I took 93 to Serbia. At that time, the whole country of Serbia had 17 suits. Every single one of them had been used before, which means there's a pretty good chance it was still contaminated. So it was making the firefighters safer, the communities of Serbia safer, and costing South Wales Fire and Rescue Service nothing at all."**

It was around the middle of last year that the team realised a similar principle could apply with healthcare organisations. "I received a request asking if we were able to help with hospital beds," remembers Steve.

The answer was yes, thanks to a South Wales hospital which was closing and leaving unneeded equipment in its wake. "So in November last year we had an articulated lorry from a Serbian transport firm arrive at the decommissioned Cefn Coed Hospital in Swansea, and we loaded it up with 65 hospital beds and 10 hospital trolleys, which were then sent out to Serbia.

"Naturally enough I asked what would have happened to these beds," remembers Steve. He was told they would have been scrapped. "So it's win/win. The trust benefits by not having to do that; the world benefits by the fact that it's not going into landfill, and Serbia benefits from receiving something which otherwise they wouldn't have been able to afford."

The gratitude of staff at the hospital in Serbian city Sremska Mitrovica is clear. "With the trolleys it's easier to transport patients and they seem to be more relaxed to sleep on those excellent beds," reports one of the nurses.

Adds hospital director Dr Živko Vrcelj: "The donation is very valuable. Beds are set at the surgery department and trolleys at the department for urgent reception. This human gesture enables us to raise the patient's treatment and comfort to a higher level and we are very grateful for the donation."

**Take a look at the photos of some of the beds used before - with sagging mattresses and broken frames - and it becomes obvious just what a difference the equipment from Wales has made.**

Hospital and fire equipment are far from the only things the Blazing to Serbia team have donated, though. They've also brought over a lot of out of date bandages from fire engines' first aid boxes.

"When young people come to the Red Cross in Serbia for first aid training, they'll use our out of date bandages for them to practise with. So it's utilising stuff that we don't want but nevertheless are needed in Serbia."

The team has also taken out old football shirts - "one of our contacts out there coaches a team, and we met on the playing fields and handed out these shirts to hundreds of kids" - and supports the Red Cross with a Christmas event for local disabled children.

**"Blazing to Serbia was never set up for that," admits Steve. "But when you're in a position to help, I feel it's almost neglectful then when you don't. It's snowballed beyond anything I could have imagined.**

"When we took our first convoy of fire engines across in 2011, we had the deputy prime minister of Serbia attend the handing over ceremony. The following year, we had the Serbian prime minister attend. Last year, we received a request to go over to the Serbian parliament to meet up with Prince Charles and Camilla."

That doesn't represent Steve's only brush with royalty. He was made an MBE in the 2016 New Year's Honours, for "services to British-Serbian relations and assistance to Serbian fire services". He says he was hugely embarrassed, but hopes the recognition will benefit both the South Wales Fire and Rescue Service and the Blazing to Serbia project.



*"I daresay there's lots and lots of stuff that people don't want that I would if the contact was made."*

And while the process of getting donations over to Serbia is not always straightforward - lorries don't come cheap, and there's customs documentation to sort out - Steve is very keen to hear from anyone who thinks they might have medical equipment they no longer need.

*"If someone said: 'We've got an elephant's graveyard of old mechanical beds here, do you want them?' Yes, I do. And somehow or other I will find the time to make that happen, and there will be no cost or liability to them and I will sort all the necessary documentation."*

Steve is in no doubt that leading the Blazing to Serbia team has changed his life. *"Genuinely it's defined the way I live my life. No ifs or buts about it. Unquestionably. Things which are important to you and I, and certainly to younger people, are completely irrelevant in Serbia."*

*"In Serbia, the reality is some people are worrying how they're going to feed their kids, not worrying about the strength of the wifi signal. It puts your life in perspective; realigns your life priorities."*

While it was pure chance that the initiative wound up focusing on Serbia - *"if that Scout leader had been to Bosnia, or Bulgaria, or Romania, or any of dozens of developing countries, then there's a good chance we would have gone there"* - Steve's affection for the place and its people has become cemented.



*"In one of our earlier visits, we went round to the home of one of the fire officers. And we met his wife and his daughter and his son, stood on the veranda in his Sunday best, and he gives us a tour and he says there's my chickens, there's my pig, there's my tractor and all this sort of stuff."*

*"And we go into his house, and his wife has made food for us, and he said fathers make special presentation bottles of Rakija [a brandy, typically home-brewed] to give to their sons to open on special occasions in their lives - getting married, the birth of a child. And he said I'd like to open a special presentation bottle of Rakija for my friends from Wales."*

*"As he's pouring it, and this is all via translators, he says: my father made this, 15 years ago before he died. Honestly, it's so humbling. And it's only after, when you reflect on what this guy did: he was prepared to give us something that he could not replace."*

*"I've been very fortunate in my life - I've been to America three times, and Spain, and so on. I have genuinely never met people who are as nice and as genuine and as hospitable as the people in Serbia. And when you're faced with that sort of attitude, it's difficult then to think: well I am in a position to help and I'm not going to."*

He continues: *"There's a very old saying which says: 'Charity, like its sister mercy, is twice blessed: it blesseth him that gives and him that takes.' And honestly I get as much out of Serbia as Serbia gets out of me. It's beyond description. It really is."*

You can find out more about Blazing to Serbia at [blazingtoserbia.co.uk](http://blazingtoserbia.co.uk), follow on Twitter [@BlazingToSerbia](https://twitter.com/BlazingToSerbia) or on Facebook: [facebook.com/blazingtoserbia](https://facebook.com/blazingtoserbia).

Steve asks anyone with potential equipment donations to get in touch: [s-logan@southwales-fire.gov.uk](mailto:s-logan@southwales-fire.gov.uk).



# Selfie

## Jean Hutfield

### What do you find most challenging in your NHS role?

Keeping within budget whilst ensuring compliance and risk are adhered to

### What has been your most significant accomplishment in your NHS work?

Being part of the team setting up the GP Out of Hours in Chester 2. Working in collaboration with Social Care colleagues to set up a different way of providing Community Equipment Services in Cheshire

### What advice would you give those starting the same career path as you today?

Listen and ensure you dot the I's and cross the T's

### What thing about your work frustrates you the most?

People given management positions that do not know anything about the service and are not prepared to listen and ask, it is not failure to ask, it prevents failure

### What changes would you like to see in the NHS relating to medical devices?

Clinical evidence, reviews and consultation before purchase

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

Put your hand in a bucket of water and pull it out - the hole that it leaves is how much you will be missed - don't forget this - you are not bigger than the job

### If you could give one message to the Brexit negotiators, what would it be?

For goodness sake get on with it and stop the negative speculation

### Why do you support NAMDET?

I am a true believer that before anyone uses any equipment they should have received and been signed off thorough training



**Age:** 73 years of age  
**NHS role and where:**

Compliance, Risk and Contracts Manager, Alder Hey Children's NHS Foundation Trust

**NAMDET role:** Director, Interim Assistant Finance Director

**National Roles:** Chair of National Association Equipment Providers (NAEP)

Chair of Community Equipment Dispensers (CED)

**Family** (names and ages of any children):

Karen Perkins, 56 years of age - Specialist Nurse

Sonia Stuart, 53 years of age - Art Technician

Leona Walker 51 years of age - Holistic Therapist

Seven Grandchildren and two Great Grandchildren

**Hobbies / interests:** Cruising, Family Get Togethers

### Why would you urge your NHS colleagues to come to the NAMDET conference?

To listen and learn what the future holds

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

To continue in the same vein encouraging articles of good practice

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

Juvenile Probation Officer

### If you were granted three wishes what would they be?

1. My children, grandchildren and great grandchildren have long and healthy lives
2. I live long enough to see my great grandchildren grow up
3. I am able to enjoy good health and continue to work

### What's your favourite book or film and why?

Lady Jane Grey - history was not kind

### What's your favourite song and why?

The Platters - The Great Pretender, I can relate to some of the words

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

My Granddad - his work ethic, his kindness and understanding gave me something to aspire to

### You have many 'hats' within various important organisations. What have you learnt from your roles outside of NAMDET and the NHS that has been

#### valuable within these organisations?

There are lots of extremely good practice out there that has enabled me to carry out my job with knowledge and understanding, you are never too old to learn and I enjoy learning

## Health Education England e-Learning for Healthcare relaunches its medical equipment e-learning programme

Health Education England e-Learning for Healthcare is relaunching its e-learning programme e4Equipment at this year's NAMDET conference.



All 50 sessions have been reviewed and updated to ensure they remain relevant to healthcare professionals and three new modules have been added to the programme; pain management pumps, basic observation/monitoring equipment and bariatric equipment.

e4Equipment is an e-learning resource for clinical staff to ensure their medical equipment knowledge is relevant and up-to-date. The project was initially set up by NHS Training for Innovation (TFI) in partnership with Health Education England e-Learning for Healthcare (HEE e-LfH); it is maintained by HEE e-LfH, and endorsed by the National Association of Medical Device Educators and Trainers (NAMDET).

e4Equipment is available in easy to use bite-sized chunks of e-learning that can be accessed at a time and place that suits.

To access the e-learning use this link:  
<https://www.e-lfh.org.uk/programmes/medical-equipment/>



**Health Education England**

## BD expands infusion portfolio



BD is pleased to announce that CME Medical UK has joined its infusion division. Bringing BD and CME UK together creates significant synergies between two established portfolios in the infusion space and sees BD expanding into the pain management and homecare sectors.

### What does this mean for BD and CME customers?

At this time, it is business as usual and there will be no changes to your current customer service, ordering, fulfilment or billing processes. Your contacts at BD and CME Medical UK will remain the same and, most importantly, we will both remain focussed on delivering the highest quality products and service that you have come to expect.

If you have any questions, please contact your current sales representative or call customer services and we look forward to seeing you at the 2017 NAMDET Conference.

### About BD

BD offers infusion and intravenous (IV) therapy systems, solutions and devices including pumps, software, interoperability, IV sets and accessories. From the hospital pharmacy to the patient bedside, we help protect every infusion for each patient.

Customer Services: 0800 917 8776  
 Email: [uk-customer-service@bd.com](mailto:uk-customer-service@bd.com)  
[bd.com/uk](http://bd.com/uk)

### About CME Medical UK

CME Medical UK is an innovator within the specialist infusion market with a heritage in developing medical infusion devices and support that improve patient care in hospital, in the community and at home.

Customer Support: +44 (0)1253 206 700  
 Email: [customersupport@cmemedical.co.uk](mailto:customersupport@cmemedical.co.uk)  
[cmemedical.co.uk](http://cmemedical.co.uk)



## Medical camera sees through the body

Scientists at the University of Edinburgh and Heriot-Watt University have developed a prototype camera that can see through the human body. Designed to help doctors track endoscopes it has been built to allow use at the bedside.

Currently, to monitor where an endoscope is located in the X-rays or other expensive methods are required. The technology in this new camera detects individual particles of light, called photons.

Light from an endoscope does pass through the body but is scattered by tissues and organs making it impossible

to get a clear picture. The new camera, by detecting both the tiny traces for light and the time taken for light to pass through the body, allows differentiation of the scattered light allowing the device to determine exactly where the endoscope is located.

Kev Dhaliwal, Professor of Molecular Imaging and Healthcare Technology, University of Edinburgh and Clinical Lead for the Proteus project believes the technology is key in supporting the increase desire for less invasive healthcare: *"The ability to see a device's location is crucial for many applications in healthcare, as we move forwards with minimally invasive approaches to treating disease."*

## "It's one small step for Nan, one giant leap for the NHS."

Utilising technology employed by NASA, the NHS is hoping to help identify older patients at risk of falls. As part of a new drive to tackle frailty the NHS is trialing wearable sensors for the over-65s.

The Perfect Patient Pathway Test Bed in Sheffield is testing Kinesis' QTUG device for patients over 65 who have no recorded falls and score as 'moderately frail'. The system sees patients walk with the motion sensor attachments on their legs while an app carries out the analysis.

The microelectromechanical (MEMS) gyroscope equipment used in the miniature devices, worn on each shin, are partly based on technological breakthroughs made through the America's space programme. The new generation of MEMS sensors are small, light and use

very little power, meaning the technology can be used to analyse human motion outside the lab for the first time. Professor Martin Vernon, National Clinical Director for Older People and Integrated Care at NHS England, said: *"It is fantastic that space-age technology, aimed at putting a man on the moon, is now helping vulnerable patients back on earth to live better while steering the NHS away from financial black holes."*

*"Frailty is an issue that has the potential to affect everyone in their later years but thanks to the work being done by the NHS to harness new diagnosis and treatment methods, the future is looking a lot brighter."*

*"It's one small step for Nan, one giant leap for the NHS."*



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# NAMDET Annual Conference

## IMPROVE SAFETY THROUGH A COMPETENCY APPROACH

2nd November 2017

The Birmingham Conference  
& Events Centre



### Conference Programme and Exhibitor Guide



### Incorporating Patient First an Introduction to NAMDET's Sessions

21st and 22nd November 2017  
at Excel, London

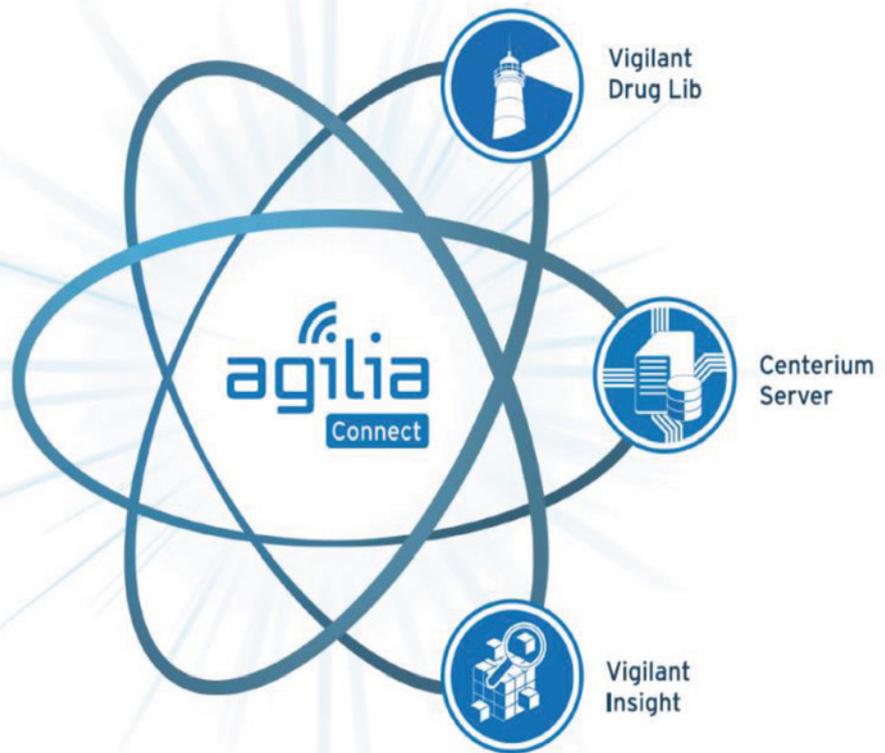




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**Andy Flood**  
Lead, Conference Committee and  
NAMDET Board Member

# Welcome

Welcome to the 6th Annual NAMDET Conference, and 2nd time here at the Birmingham Conference and Exhibition Centre. I hope you will enjoy the conference and take advantage of the opportunity to network with colleagues from all corners of the United Kingdom and Ireland.

As I am now retired, this is my 4th and last conference as conference organiser. The programme we have put together covers all aspects of Medical Device Training and Safety from a competency point of view. so, there is plenty to keep you interested.

We have had the best response to date from companies wishing to exhibit at this years' event, and I would encourage you to visit each stand to see what they have to offer.

Details of our 2018 conference, which we hope to hold in Manchester in November, will be available soon.

Many Thanks

**Andy Flood;** ODP; FCOOP; MSc; Dip.Trng Mgt; Cert MHS;ENB 925, Cert Op. Dept. Nursing

*on behalf of the conference committee*





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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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# NAMDET Annual Conference 2nd November 2017

## The Birmingham Conference & Events Centre

Reduce Costs • Manage Quality • Improve Safety through a Competency Approach

08.45 - 09.20

*Registration and Refreshments*

Morning Session

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09.20 - 09.30

Chair: Mr. Graeme Kirkpatrick, Head of Patient Safety (Advice & Guidance) NHS Improvement

---

**Welcome and Opening Address**

Andy Flood, Conference Organiser & NAMDET Chair, Paul Lee

09.30 - 10.10

**Keynote Address:**

“What have we found so far to date and implications for Providers”

Ellen Armistead, Deputy Director, CQC

10.10 - 10.45

**Update on Credentialing**

Dr, Michelle Dawson, Clinical Lead, Credentialing Group

NAMDET Management Committee

10.45 - 11.15

*Refreshments and Networking*

11.15 - 11.50

**Medical Device Incidents and the Coroner**

Ana Samuel, specialist in clinical negligence, Assistant Coroner for Birmingham and Solihull

11.50 - 12.25

**e-learning v face to face training**

Ruth Goodwin, Clinical Education Manager

and Ginina Houghton, National Clinical Manager, CME Medical

12.25 - 13.30

*Lunch and Networking*

Afternoon Session

---

Session Chair: Dr. Douglas Clarkson, West Midlands Branch Chair

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13.30 - 14.05

**Digital literacy; Why it matters and how we are working to improve capabilities in health and care staff?**

Susan Kennedy, Educationalist and Digital Literacy Lead, TEL Programme, Health Education England, & Building a Digital Ready Work Force Programme, National Information Board

14.05 - 14.40

**Standardisation of dual infusion practice and peripheral cannulas**

Janet Clegg, Curriculum Development Co-ordinator within Education, & Nicola Nicholls, Associate Director Nursing Assurance and Compliance, Pennine Acute Trust

14.40 - 15.15

**Compliance & Governance -Learning from the private sector**

David Coverdale BA(Hons), Senior Consultant, Egton Digital

15.15 - 15.45

*Refreshments and Networking*

15.45 - 16.15

**How NAMDET proposes to establish National Competencies**

Marie Law and Tammy Marsh, NAMDET Management committee

16.15

**Chairs, Closing Remarks & Look Forward to Conference 2018**

Supporting you  
through every step

# B. Braun Space

Administration Safety with Real-time Clinical Insights  
and Improvements

**DoseGuard** – Helps to protect patients and nurses from harmful medication errors.

**DoseTrac** – Real-time reporting creating insights into potential medication errors.

**Upload Manager** – Remote, real-time upload of DoseGuard libraries to all Space infusion devices.

## Health Education England e-Learning for Healthcare is relaunching its e-learning programme e4Equipment at this year's NAMDET conference.

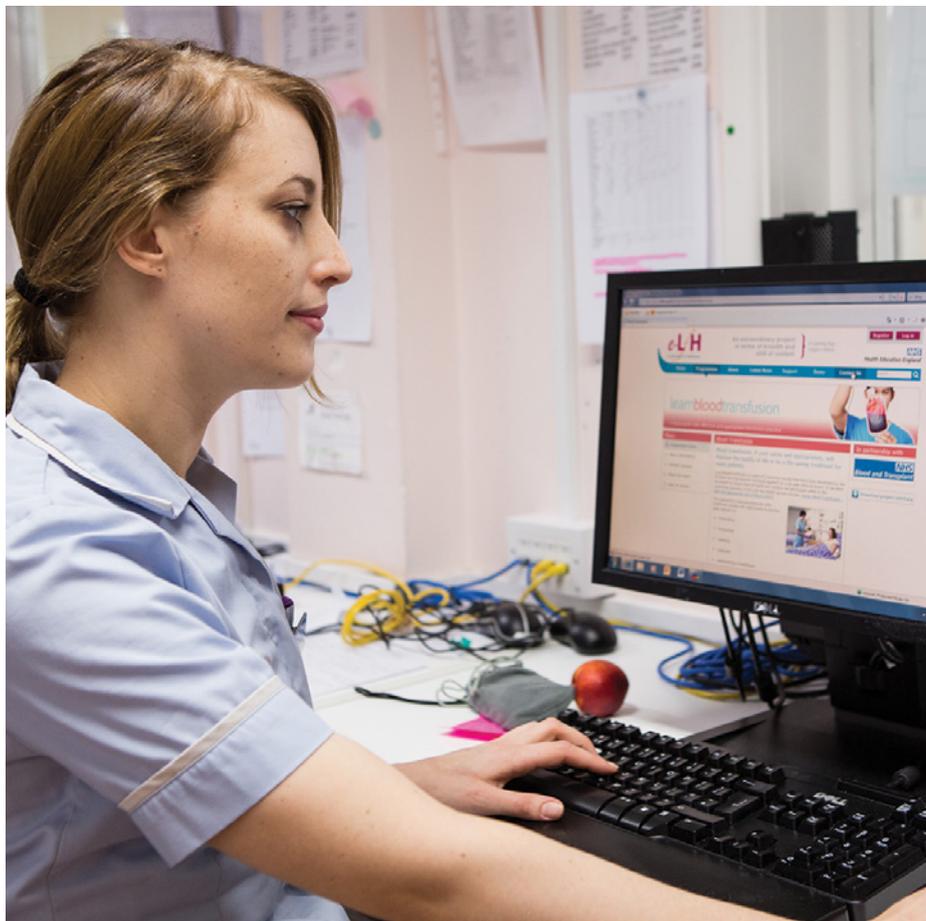
All 50 sessions have been reviewed and updated to ensure they remain relevant to healthcare professionals and three new modules have been added to the programme; pain management pumps, basic observation/monitoring equipment and bariatric equipment.

e4Equipment is an e-learning resource for clinical staff to ensure their medical equipment knowledge is relevant and up-to-date. The project was initially set up by NHS Training for Innovation (TFI) in partnership with Health Education England e-Learning for Healthcare (HEE e-LfH); it is maintained by HEE e-LfH, and endorsed by the National Association of Medical Device Educators and Trainers (NAMDET).

Aimed at all healthcare professionals within NHS Trusts, e4Equipment provides high quality training in the safe and effective use of medical equipment technology. The resource can be integrated into existing training programmes and complemented by practical workshops. Content has been based on best practice advice.

The development process has included consultation with medical equipment trainers, and national bodies such as the Medicines and Healthcare products Regulatory Agency, National Health Service Improvement (Patient Safety), Care Quality Commission, National Health Service Litigation Authority and Standards for Better Health.

**e4Equipment**  
e-Learning for Medical Equipment Training



e4Equipment is available in easy to use bite-sized chunks of e-learning that can be accessed at a time and place that suits.

To access the e-learning follow this link:  
<https://www.e-lfh.org.uk/programmes/medical-equipment/>



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# Speaker Biographies

## Ellen Armistead -

Deputy Director CQC



**Keynote Address:** "What have we found so far to date and implications for Providers"

Ellen is currently a Deputy Chief Inspector for hospitals with specific responsibility for community care. She is the former Chief Executive of Lincolnshire Community Health Services NHS Trust. Having previously worked in the acute sector, the last seven years of Ms Armistead's career have focussed on community health. Her community services include community nursing and therapy services, primary care, urgent care centres, community hospitals, sexual health, and smoking cessation as well as children and family services. Also, Ms Armistead brings her professional experience from her background in nursing. She has worked for the CQC as a specialist advisor.

## Dr Michelle Dawson -

Clinical Lead,  
Credentialing Group



**Update on Credentialing**

Dr Michelle Dawson, BSc, MB, BS, FRCA. Graduated from St Bartholomew's Hospital, London. Consultant Anaesthetist at Derby Teaching Hospitals NHS Foundation Trust with interests in peri-operative care, regional blocks, bariatric and one lung anaesthesia. Clinical lead in Procurement since 2011.

## Ana Samuel -



**Medical device incidents and the coroner**

Ana specialises in Clinical Negligence, Personal Injury, and Employment law. Ana also undertakes both free standing inquests and those linked to clinical negligence and personal injury claims.

**Year of call:** 2004

**Appointments:** Assistant Coroner to Birmingham and Solihull

**Memberships:** PIPA, Coroners' Society of England and Wales

**Publications:** Clinical Risk: 'Habeas Corpus? Body or Evidence?' Clinical Risk: 'She should have died hereafter.'

**Affiliations:** [www.Pro-videre.co.uk](http://www.Pro-videre.co.uk)

**Other Qualifications:** Mediator

### Clinical Negligence

Ana frequently represents both Claimants and Defendants (NHSLA and private individuals) in clinical negligence actions undertaking advisory, drafting and advocacy work.

Ana has spent time working in the legal department of a major insurance company and thus understands litigation from the perspective of an the insurer as well as that of the individual client.

Ana deals with all nature of hearings from interlocutory matters through to JSM and final hearing.

Ana has recently handled to conclusion a clinical negligence case pleaded in excess of £1.2 million, appearing against a specialist clinical negligence Silk.

### Recent areas dealt with include:

- Tears during childbirth
- Disruption to the pelvic girdle following childbirth
- Development of Compartment syndrome following childbirth
- Damage to optic nerves due to over pressurizing the eyeball
- Tears and detached retinas caused during ophthalmic surgery
- Failure to diagnose heart failure
- Failure to refer a patient under the NICE cancer guidelines
- Failure to provide nutritional advice following a gastric bypass
- Failure to consent • Overdose of medication
- Failure to section under the mental health act
- Negligent decompression surgery
- Negligent Hip replacement • Delay and/or failure to diagnose
- Surgical negligence in a wide range of clinical specialisms
- Dental negligence • Cosmetic surgery • GP negligence
- Failure to advise patient of alternative less invasive options
- Failure to provide antibiotics resulting in fatal sepsis
- Fatal accidents claims based on clinical negligence actions
- Cauda Equina cases



## Speak to us today

about device training management systems and its wider role in compliance and risk management.

### Ruth Goodwin



#### e-learning v face to face training

Ruth joined CME Medical in 2007 as a Clinical Support Specialist and changed roles to become responsible for designing and developing infusion pump user guides and clinical education programmes.

As a qualified RGN, Ruth previously specialised in Critical Care Nursing and resuscitation training in the UK and spent several years working abroad. Ruth's interest in medical device clinical education developed whilst working abroad and on returning to the UK in 1997 Ruth completed further training and qualifications, including quality management and technical authoring to become specialised in this area of expertise.

### Ginina Houghton

RGN, Diploma in Adult Nursing;  
Mentorship Level 3; PTTLs



#### e-learning v face to face training

Ginina is the National Clinical Manager at CME Medical UK, managing a team of Clinical Support Specialists.

Ginina has over 17 years of healthcare experience ranging from complex care and high dependency in both the acute and community setting. Eight years were spent in the NHS and the last nine years in the commercial sector as a Nurse Advisor, Clinical Trainer, and Clinical Manager.

On qualifying as an Adult Nurse, Ginina completed further courses in Mentoring and Teaching.

## Susan Kennedy -

Educationalist and Digital Literacy Lead, TEL Programme, Health Education England



### Digital literacy; Why it matters and how we are working to improve capabilities in health and care staff?

Susan is Educationalist and project manager working at Health Education England (HEE). Currently, I am Project Lead on the national Digital Literacy Project which is part of both the Technology Enhanced Learning (TEL) and Building a Digital Ready Workforce (BDRW) Programmes. This project aims to improve the capability and culture in the workforce to support the better use of data, information, knowledge and technology for better health and care outcomes.

Previous work has included leading on the development of the curriculum framework documentation for the new nursing associate role; leading on

broadening the foundation programme for training doctors and undertaking curricula review as part of the Modernising Scientific Careers Programme.

Before working for HEE, I worked as an educationalist in a local NHS trust with a remit of improving the quality of teaching and learning of medical students, training doctors and senior faculty.

Originally, as a trained teacher, I worked at senior level in secondary and higher education at both schools and university, teaching history and politics.

My career has also seen me work as an independent education consultant providing educational research, strategic reports, workshop facilitation and project management.

**Specialties:** Project management, teaching, curriculum planning, review and mapping, educational research, strategic planning, leadership and management consultancy, workshop facilitation, team building, social media.taught. The programme rapidly became a significant income generator for the university.

## Janet Clegg

PGCE, Bsc (Hons) RGN



### Standardisation of dual infusion practice and peripheral cannulas

Janet is the Curriculum Development Co-ordinator within Education specialising in Medicines Safety & IV Therapy for the Pennine Acute Hospitals NHS Trust.

Janet worked as a ward sister on the ophthalmology unit for several years prior to moving into clinical education; Janet is responsible for planning, reviewing, teaching and evaluating programmes in one the largest NHS trusts in the country. Janet is currently on secondment to assist with quality improvement within the surgical division at North Manchester General Hospital.

## Nicola Nicholls

Associate Director Nursing Assurance and Compliance for Pennine Acute NHS Trust



### Standardisation of dual infusion practice and peripheral cannulas

Nicola has gained experience in a number of management and senior nurse roles, as well as leading on a variety of organisational wide change projects. Her current role involves policy & quality development, standards, and compliance monitoring.

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### David Coverdale -



“Compliance and Governance” - learning from the private sector.

Compliance and governance impacts on all areas of an organisation. Ultimately where there is data, in this case medical device training and usage, there is value. By being able to truly manage and report on these often complex areas, you can begin to realise the true strategic impact on your organisation.

- Delivering valuable information in complex structures
- Enabling insights without creating a new industry
- Influencing culture and behaviour to achieve change
- The value of technology as an enabling force

David has had an extensive career in Business Continuity and Risk Management consultancy, training, and software, creating and launching [www.bcp4me.co.uk](http://www.bcp4me.co.uk) in 2008 with many Blue-Chip clients and the Public Sector.

He was a lead practitioner of TQM in which he applied the principles of continuous improvement to senior roles in Xerox, Sharp Electronics, and Pace Micro Technology, before running his own business, and joining PinBellCom limited in 2013.

At PinBellCom he was involved in the successful award submission for the GP awards from 2012 to 2016 and also the CIR and BCI awards for innovation with

TheOneView platform in 2014 to 2016. He took on the development of the MELVIS training verification system with Leeds TH in 2015 and still consults in this area.

David works with Egton and EMIS PLC on governance and compliance issues and promotes software platforms to commercial and Public Sector clients.

# NAMDET Board and Management Committee

PAUL Lee -



NAMDET Chair

In 1986, Paul completed his apprenticeship and HNC in Electronic Engineering and started his NHS career as a medical technical officer in Cardiff Royal Infirmary. He worked for 17 years as a medical electronics engineer and in 2003 he was appointed as the lead for medical device training in Swansea and currently works in Morrision Hospital, ABM University Health Board (Abertawe Bro Morgannwg) leading the medical device training team in one of the largest health Boards in Wales. He is the chairman of his organisation's Infusion Devices Group and ENFit (Enteral Feeding Connectors) group, as well as being a member of the Safer Sharps Group, Neuraxial connectors group, paediatric risk committee, product evaluation group, medical devices committee and medicines policy review group.

During his NHS career, he has delivered training to over 10,000 staff, designed and developed a range of training tools, teaching aids, drug calculation software, training booklets, videos and quick reference guides. In 2010, he co-developed and launched the 'ivDrip rate' app which has sold all over the world.

Paul also has a diploma in leadership and management plus a first-class honours degree in education and training. He has written and published articles on equipment management and his work around infusion therapy and presented his research work at many national and international conferences.

From February to September 2017 Paul was seconded to NHS Improvement as the Patient Safety Lead for Medical Devices and worked on a number of key projects including; Patient Safety Alert & supportive information for Neuraxial connectors and coroners reports on alcohol hand gel and portable oxygen cylinders safety. He is now a

member of the National MDSO Editorial Board and recently appointed to NHS Improvement National Patient Safety Response Panel.

Paul is also a member of IPEM's (Institute of Physics and Engineering in Medicine) Clinical Engineering Special Interest Group (CESIG), a CPD auditor and Moderator for their Clinical Technologist training programme.

He is well published and his specialist area of infusion devices and IV therapy has helped him develop training programmes in this high-risk area. He has shared his research work around the world and also peer reviews articles for national journals. He was an advisory board member for the CHI+ MED (Computers and Human Interfacing with Medical Devices) international research project looking at usability of medical devices, front panel designs, error logs and Drug Error Reduction Software (DERS)

Paul is currently Chairman of the NAMDET board and helps develop the new website including regular posts, news updates and alerts and dealing with members queries.

Mike Peel -



Lead Area: Communications and Education

Mike Peel (Rtd) worked at the MHRA for 14 years in many roles and was Project Manager on the Unique Device Identification Track & Trace development for MHRA, working with DH team, NHS England, GS1, HSCIC, ABHI and numerous NHS Trusts and private healthcare providers. This project was aimed at encouraging trusts to adopt and integrate implantable medical device UDI barcode data into patient HES data. The project supports the DH E-Procurement Policy and HSCIC's ongoing patient safety projects.

Mike was also PM on the Certificate of Free Sale (CFS) transfer into the MHRA portfolio. The DoH has managed the CFS project for over 25 years. CFS supports UK PLC medical device manufacturers and helps them market their products in countries outside the EEC by providing certificates of compliance.

The project move is a relatively simple 'Lift and Shift' but will then require extensive working to ensure that it fits into the Medical Devices project plan.

Mike also leads and manages Namdet's Medical Device Driving Licence MDDL project which integrates the medical device e-learning modules under one platform.

The MDDL is free to use and can be accessed at [www.mddl.org.uk](http://www.mddl.org.uk)

Mike has been on the NAMDET board as Communications Director from the launch of the National project following his work with TFI and E4EL.

## John Byrne -

Treasurer



John has worked within medical devices management and maintenance for over 20 years.

He trained as a medical and dental technician at the School of Electronic Engineering, whilst serving 22 years in the Armed Forces. The last 9 years he has spent managing clinical engineering departments in Gosport, Brunei, The Falkland Islands and Gibraltar, as well as setting up clinical engineering departments in Kosovo and Afghanistan. John created the policy document for all of the medical staff in all medical facilities in Afghanistan. This policy was still in force until the closure of the hospital and was the benchmark for total quality inspections.

John was a total quality inspector for all medical services in Germany, Holland and Belgium.

He specialised in working with failing health centres, advising clinical staff on the best practices to continuously improve their management systems. This employed the principles of Total Quality Management and incorporated policy standards governing medical devices.

After John left the forces, he worked for a third party maintenance company as their UK Consultancy Manager, setting up and specialising in Medical Devices Training at many Trusts, as well as completing high level audits of medical devices management at NHS Trusts, in the UK and abroad. He was also responsible for advising Trusts, Acute and Community Services, on the management of medical devices, in order to comply with the former risk management standards of the National Health Service Litigation Authority (NHSLA) and the Health and Social care Act 2008 (Regulated Activities) regulations 2014.

At an inspection of the first site he project managed, the NHSLA inspector described the procedures as 'exceptional' and 'the best they had inspected'. This facilitates the Trusts by not only having huge cost

savings, but an improved and safer patient care.

John also provided interim EBME management to Trusts that required improvement, both internally and externally to the company.

John is currently working as the Field Service Trainer at Arcomedical Infusions Limited. He created, updates and teaches training packages for technicians at various Trusts. These training packages have to be individualised for each Hospital / Department, owing to the various settings that are on offer. He also updates the software for pumps to ensure the changes that are required by the Trust are implemented. This includes the drug library of the pumps, in order that the correct drugs are set for the Trust, Dose Error Reduction Software (DERS)

John helped to set up and was the chairperson for the London and South East Region of the National Association of Medical Devices Educators and Trainers (NAMDET), from April 2011 to February 2015. He is a Director at NAMDET and provides advice and assistance to Trusts on Medical Devices training.

## Andy Flood -

(Rtd)



Lead Area: Conference Chair

Qualifications:- Reg ODP; F.I.O.T; MSc; Dip Trng Mgt; Cert HSM; FETCert; ENB 925. Andy Flood (Rtd) Has over 40 years experience working within an Operating Theatre and Critical Care Environment.

Andy worked as Medical Equipment Training Coordinator within the Sheffield Teaching Hospitals NHS Foundation Trust. The Trust covers 4 adult hospitals, and Andy liaised with the Sheffield Children's Hospital NHS Foundation Trust, and the Sheffield Primary Care Trust.

He has a clinical background as a Registered ODP, and is also military trained as an Operating Theatre Technician (Class 1). Andy has over 25 years experience within a military setting rising from the rank of Private to Lieutenant, seeing Active Service in the first Gulf War with the RAMC. In 1998 Andy was awarded the Fellow of BAODA (formerly Institute of Operating Theatre Technicians). Andy also hold a English National Board 925 Certificate in Operating Theatre Practice.

In 2009/10 Andy was seconded to Training for Innovation (TFI) to lead a national team (E4e) for the development of learning programmes with eLearning

for Healthcare (eLH). Over 40 programmes were developed and are now on the National OLM Platform.

Andy's post basic qualifications are in Management & Training, gaining an adult Further Education Teaching Certificate and a Certificate in Managing Health Services. In 2003 Andy was successful in gaining a Diploma in Training Management and then completed a Masters in Health and Social Care Leadership in 2012. Andy has held posts as Operational, and General Manager, within Operating Theatres and Training Manager of regional Schools for Operating Theatre staff.

## Jean Hutfield -



### Lead Area: Specialist Advisor (Primary Care)

Jean Hutfield, Chair of NAEP. Having been a member of NAEP since its conception in 1999 and witnessing the year on year growth of this national Association, I am very proud to be the Chair of such a noteworthy and growing organisation.

I have been fortunate to enjoy an extensive career within the NHS spanning 38 years, 35 years in Community Services and currently part of the management team as Compliance, Risk & Contracts Manager within Alder Hey Children's NHS Foundation Trust.

In addition, I hold the post of Chair of the Community Equipment Dispenser (CED) Accreditation Board. Formed in 2007, the CED accreditation scheme was established as the first registration scheme and accreditation body to champion the provision of a quality assured prescription based dispensing service for the Community Equipment Services Retail Model. This was not only an accreditation body for prescriptions, but open to all Retail establishments throughout the United Kingdom to provide a quality assured Retailer.

Earlier this year, as a long standing member of the Board of Assist UK and more recently as Chair, I was bestowed the title of Honorary President of Assist UK.

As a NAMDET Board Member, I am the Director of New Business Development - with a keen affinity to developing working partnerships to progress the integration and development of innovation and training throughout the Healthcare sector, I aspire to bridge the Acute and Community sectors with the sharing of all 'medical device training and education' initiatives emanating from NAMDET.

As a member of the Institute of Healthcare Management (IHM), which has now joined with the Royal Society for Public Health, I look forward to sharing the membership benefits of this institute specifically developed to meet the changing needs of the healthcare sector.

## Rose Parker -



### Lead Area: Membership and National Liaison

Rose is a Registered Nurse who trained in Liverpool before completing her Post Graduate studies in Midwifery, Ear Nose and Throat Surgery, Head and Neck Surgery, Neurosurgery and Intensive Care. Following graduation Rose was employed in London for a year before moving to Europe. There she worked as an Intensive Care Sister in Holland, Germany, Gibraltar, Scotland and back in London. From there she subsequently emigrated to Australia and accumulated over twenty years of experience in teaching and management posts before returning to Liverpool, from where she started. Rose now works at St Helens and Knowsley Teaching Hospitals NHS Trust as Medical Devices Training Co-ordinator, where she established the Northern Best Practice Medical Devices Group in January 2008

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## Dr. Michelle Dawson

BSc, MB, BS, FRCA



### NAMDET Management Committee

Michelle has been a Consultant Anaesthetist at Derby Teaching Hospitals Foundation Trust since 2001 with special interests in perioperative care, regional blocks and bariatric anaesthesia. She has been clinical lead in procurement since 2011, helping to deliver savings of over £1.4 million per annum.

Michelle has been working with NHS England for the past two years on their project to develop a professional governing body for healthcare industry representatives as the clinical representative on that project.

## Marie Law -

PGCE BSc (Hons)  
Dip App Soc Sci, RGN



### NAMDET Management Committee

Marie is the Medical Device Governance Manager at Pennine Acute Hospitals NHS Trust. She worked as a Ward Manager for 18 years, before moving into Clinical Education. In 2010 Marie was asked to look at improving the Trust's compliance with national standards for medical devices. This work resulted in the establishment of the Medical Device Governance Department which integrates device training with safety and management.

## Tammy Marsh -

PGCE, Bsc (Hons), RGN



### NAMDET Management Committee

Tammy is the Medical Device Training Coordinator for Pennine Acute Hospitals NHS Trust. She began her health service career as a Theatre Practitioner, where she developed an interest in education and training. Tammy moved to a post as an Education Training and Development Programme Coordinator, before taking up her current role in 2011. She is responsible for the trust training needs analysis as well as training programme and assessment quality.

## Rob Matthews -



### NAMDET Management Committee & Chair Wales Branch

Robert was an apprentice trained in the electronics industry from leaving school. 18 years ago the opportunity presented itself to leave private industry and join the NHS as a Medical Technical Officer. For the past 7 years Robert has been a Medical Devices Training Officer, delivering training to all grades of staff for all infusion devices, laser safety management and medical gases. Amongst other duties Robert manages the medical devices library across 2 acute hospitals, advises on an expert panel for all Wales procurement for a range of devices, acts as a medical alerts safety officer for the Health Board and is an assessor for the Nation School of Healthcare Science for the MSc scientists programme in the Clinical Engineering field. He was asked to Chair the Welsh branch in 2014 and has grown the members to over 30 to date.

# NAMDET Branch Chairs and Secretaries

(Please visit the NAMDET website for latest branch information)



**Richard Olver - Chair,**  
**North West Branch**

**Luke Kennedy - Secretary**

## **Douglas Clarkson -** **B.Sc., M.Phil., Ph.D** **Chairman,** **West Midlands Branch**

Douglas' current main role is as Medical Devices Safety Officer in University Hospital Coventry and Warwickshire NHS Trust where he has roles of Chairman of Medical Devices Safety Committee, the Medical Gas Committee and the Lasers and Non-Coherent Optical Radiation Committee. Current areas of development/ involvement include the progressing of the 'Medical Device Guidebook' system as a Trust wide resource for medical device users and also determination of drug delivery characteristics of syringe drivers as single or multiple devices operated at a range of flow rates. Also has an active role in medical equipment management as Quality representative of MEBS ISO13485:2016 quality management system, where there is an increasing use of risk metrics in developing systems for medical equipment management.



## **Rebecca Delpino -** **Secretary, West** **Midlands Branch**

Rebecca's background within nursing has, for over twenty years, predominately been within both orthopaedic / surgical clinical areas; before undertaking a secondment within the professional education department at Heart of England NHS Trust (HEFT) in 2013 for a year. In June 2015 she was appointed into an Educator's position within the Medical Device team at HEFT and has recently become a member of NAMDET. Rebecca is now acting as secretary for the West Midlands Regional Group, alongside her colleague as Chair.



Rebecca's interest and enthusiasm for Medical Devices has grown and is still developing. Through the contacts made at her first NAMDET meeting, she is inspired by others and shares their drive and commitment to promote patient safety and high standards of patient care.

Rebecca works full time in an Educator role and is in the process of completing a MSc in Education & Healthcare Practice at Wolverhampton University.

## Gill Hart - Chair North East Branch



I qualified as a staff nurse in 2002 and have worked within Critical Care in Newcastle for the last 15 years. I studied and gained my degree from the University of Northumbria in 2008 and became a Clinical Nurse Educator in 2012, this is when the wonderful world of medical devices was revealed! I was given the role of medical devices lead for the Critical Care directorate and have acted as chair of the group for the last 5 years. As a group we have developed central access to all medical devices competencies within the Trust and act as a link to the main Medical Device Steering Group. This year I was introduced to NAMDET quite by chance and have been voted as Chair of the North East Regional group.



## Chris Maddox - Secretary North East Branch



I qualified with a degree in Occupational Therapy from the University of Northumbria in 1993 and have worked in the North East ever since, spending the last 20 enjoyable years in beautiful Northumberland. I have worked across health and social care settings with people who have a physical disability, specialising in stroke rehabilitation in my later clinical years. I moved into a training role a couple of years ago, both organising and delivering training sessions for equipment provided by the joint loan equipment stores in North Tyneside and Northumberland and then into the role of medical devices training coordinator for Northumbria Healthcare Trust. Not a lot of people know this yet but I am to move into the role of medical devices safety officer for my Trust, I'm very excited for this move as it will allow me to promote the safe use of medical devices in a different way and I know I am passing the training coordinator baton to another NAMDET member with a very safe pair of hands.



## Sarah Seilly - Chair NAMDET Yorkshire



I am the Lead Clinical Application Specialist for the Surgical Energy Team in Olympus. My background is both RGN and RSCN and I have worked for Industry for the last 17 years.



I have a passion for Training and Education and ensuring both Industry and Clinicians are working together to achieve the desired results.

## Mary Caddis - Chair London & South-East Branch.



Mary Caddis, Lead Medical Device Trainer, Barts Health NHS Trust

Mary is delighted to be regional chairperson for this active and lively group who have been meeting regularly for more than 5 years.

During this time London Branch has been lucky to attract and learn from a variety of speakers who have shared topical issues as well as members sharing their local experiences. In April this year the branch hosted a very informative MHRA/NHS England Roadshow. The group have also worked on a CQC audit tool and explored the latest software for planning, recording and reporting medical device training.

The aim of NAMDET London and South East is to create a forum which facilitates effective and beneficial networking, mutual support and dissemination and sharing of best practice to make medical devices and their use more effective and safer for both patients and staff. Our meetings are always well attended by Medical Device Educators and Trainers from the NHS, private sector and industry and we always welcome new members and those from other parts of the country to join us.

## Bev Curtis - Secretary NAMDET Yorkshire



Bev is currently working as the Medical Devices Safety Officer and Equipment Library manager at Harrogate & District NHSFT.



Her background is 9 years working as a Medical Devices trainer and 13 years as a registered nurse (4 years in surgery and 9 years in intensive care).

**Janine Webster -**  
MBA BA  
Chair South West Branch



The South West Group includes Cornwall and Devon health care organisation. It has members from the community as well as acute trusts.

Janine spent the first part of her career working for Massachusetts General Hospital, located in Boston Massachusetts, USA, as a Biomedical Technician working with clinical staff in the critical care environment while completing her BA in Electronic Engineering Technology. Her primary role was maintaining the medical devices, teaching staff how to use them and offering expert advice with long term procurement planning. She advanced to a Clinical Engineering position and then became involved in large scale planning of the installation, procurement of devices for new hospital wards, running the maintenance programme for the organisation as well as overseeing five intensive care units as the primary engineer.

Janine also worked alongside Harvard University Engineering students to assist in developing engineering

projects for special needs patients in clinical care settings. After moving to the UK and taking time out to raise a family, Janine joined the NHS (Royal Cornwall Hospital) as the Medical Devices Training Officer. During this time she developed a 12 month continuous running medical device training programme for permanent staff as well as part time flexible staff. She has developed new tools to monitor staff compliance which are currently being implemented and adapted in various trusts across the UK. Years of working in health care (US and UK) has given her insight and expertise with the relationship between medical devices and their users. She is very interested in innovation ideas and is currently working on lean innovation projects to reduce the level of assets used in her organisation. She has recently completed her Master in Business Administration and is taking a welcome break from education.



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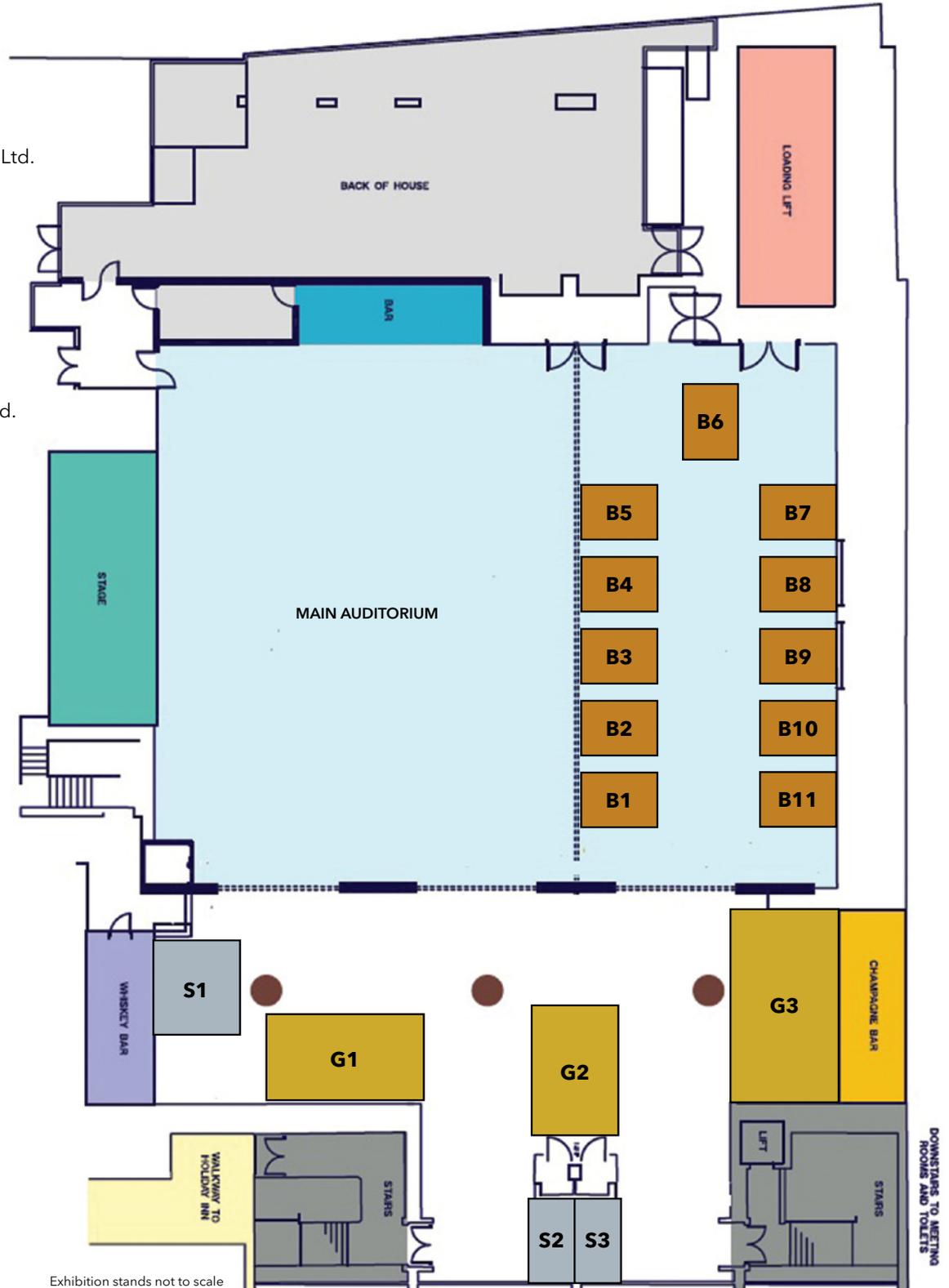


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## CME Medical UK Ltd

We believe in making clinical practice safer and more efficient. Our heritage is in developing specialist medical infusion devices and support that improve patient care in hospital, in the community and at home.

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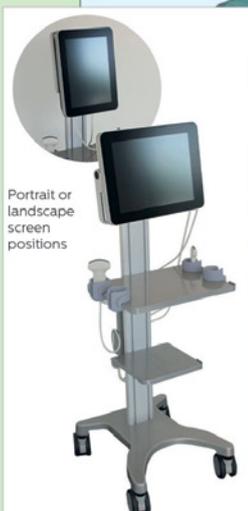


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## Vygon (UK) Ltd

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1. Study by Imperial College Healthcare NHS Trust

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NAMDET is pleased to be supporting and partnering with Patient First, the UK's largest patient safety event, at London's ExCeL on Tuesday 21st & Wednesday 22nd November 2017.



**Paul Lee**  
NAMDET Chair

A number of key speakers and experts will be sharing their own personal experiences, as well as presenting their talks around key themes in 8 different sessions over the 2 day event. NAMDET attended the event last year and we were extremely pleased to be invited back as a key contributor, and this year we'll have our own education training events within the conference itself.

Our colleagues and NAMDET members will be presenting updates on patient safety, risk, infusion device errors, drug error reduction software, oxygen & medical gas safety, new ISO connectors in healthcare, reps credentialing systems, and 'scan for safety' updates.

NAMDET is presenting in association with colleagues from healthcare, NHS Improvement and industry and we can be found at the 'Medical devices and medicines safety theatre'. The sessions are aimed at medical device trainers, medical device safety officers (MDSO), medical equipment managers, risk and governance managers and clinical staff that work in safety, education and training.

Over 3,000 people are expected to attend this year's event and this is unmissable for anyone involved in the improvement of patient care nationwide.

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# PATIENT FIRST: NAMDET Medical Devices and Medicines Safety Theatre

Time	Tuesday 21st November 2017
09:45 - 10:15	<b>How to avoid legalities around medical devices and bad judgement</b> <i>Derek Hamill</i> Senior Solicitor, Gilson Gray LLP <i>Anne Rhodes</i> Senior Lecturer and Theatre Manager NHS Scottish Healthcare
10:25 - 10:55	<b>What MHRA does for patient safety, how it works and what it can't say!</b> <i>Kendal Harrison</i> MHRA
11:20 - 11:50	<b>SAFE - automate to safeguard against frontline errors</b> <i>Ed Platt</i> Director of Automation Sales, Omnicell <i>Lauraine Gibson</i> Modern Matron Emergency Care Northumbria Healthcare NHS Foundation Trust
12:00 - 12:30	<b>Can e-Learning and self-declaration really be safe? Launch of the newly developed MDDL - Medical Device Driving Licence</b> <i>Mike Peel</i> Director NAMDET <i>Tom Clutton-Brock</i> Clinical Director, NIHR Trauma Management Health Technology Cooperative; Reader in Anaesthesia & Intensive Care; University Department of Anaesthesia & Critical Care, Queen Elizabeth Hospital Birmingham
12:40 - 13:10	<b>Respiratory rate: How can we get more out of this important vital sign data</b>
14:00 - 14:30	<b>Infusion pumps - common errors and how to avoid them</b> <i>Paul Lee</i> National MDSO, NAMDET Chair
14:45 - 15:15	<b>Metrics for understanding medication error</b> <i>Gillian Cavell</i> Consultant Pharmacist and Deputy Director of Pharmacy, Medication Safety King's College Hospital NHS Foundation Trust
15:30 - 16:00	<b>A dash for communication</b> <i>Jonathan Bevan</i> E-Prescribing and Medications Safety Lead, The Christie NHS Foundation Trust
16:15 - 16:45	<b>MSOs in community pharmacy</b> <i>Janice Perkins</i> Pharmacy Superintendent, Well
17:00 - 17:30	<b>Dose error reductions - does it save lives? Why is it not mandated? Panel discussion chaired by</b> <i>Rob Matthews</i> NAMDET National Working Group

# PATIENT FIRST: NAMDET Medical Devices and Medicines Safety Theatre

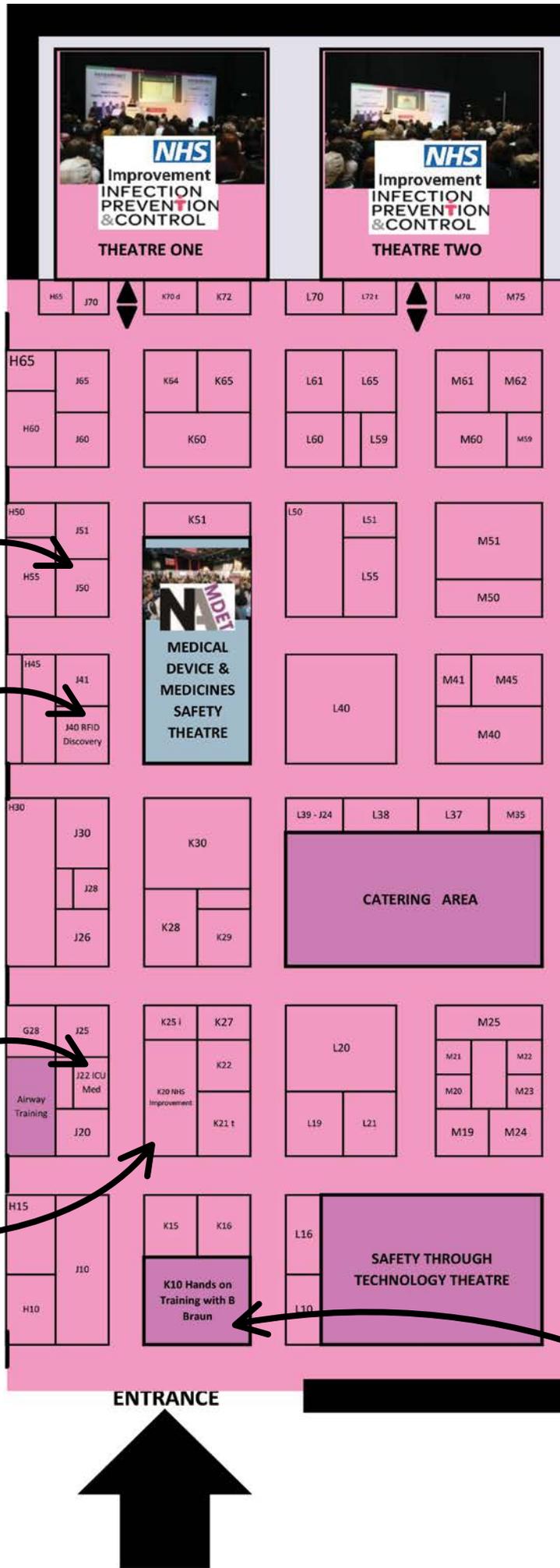
Time	Wednesday 22nd November 2017
09:45 - 10:15	<b>Improving medicines safety in a Mental Health Trust: a role for all healthcare professionals</b> <i>Seema Shah</i> Medicines Safety Officer, West London Mental Health NHS Trust
10:30 - 11:00	<b>Gas or air doctor</b> <i>Rob Matthews</i> NAMDET National Working Group
11:05 - 11:25	<b>An introduction to the PAL Sleeve - Pre-Anaesthetic Limb Sleeve</b> <i>Jamie Munro</i> Sales Manager, Pentland Medical Ltd.
11:30 - 12:00	<b>Manufacturer rep credentialing - the latest information</b> <i>Dr Michelle Dawson</i> Consultant Anaesthetist, Royal Derby Hospital <i>Andrew Davis</i> Association of British Healthcare Industries (ABHI)
12:15 - 12:45	<b>Acute patient diagnosis: How can we use vital sign data, trends and observations more effectively?</b>
13:40 - 14:10	<b>The challenges of error in information technology</b> <i>Ann Slee</i> ePrescribing Lead, Digital Technology, NHS England <i>David Gerrett</i> National MSO, NHS Improvement
14:20 - 14:50	<b>Micro and leur connectors: most common issues and how to help eradicate them</b> <i>Paul Lee</i> NHS Improvement Neuraxial Oversight Group
15:00 - 15:30	<b>Safer use of antibiotics in patients with allergies</b> <i>Dr Yogini Jani</i> Consultant Pharmacist Medication Safety, UCLH NHS Foundation Trust
15:45 - 16:15	<b>Scan4Safety and medical device procurement - latest update from a demonstrator trust</b> <i>Sarah Jennings</i> MDSO and Decontamination Lead, Salisbury NHS Foundation Trust

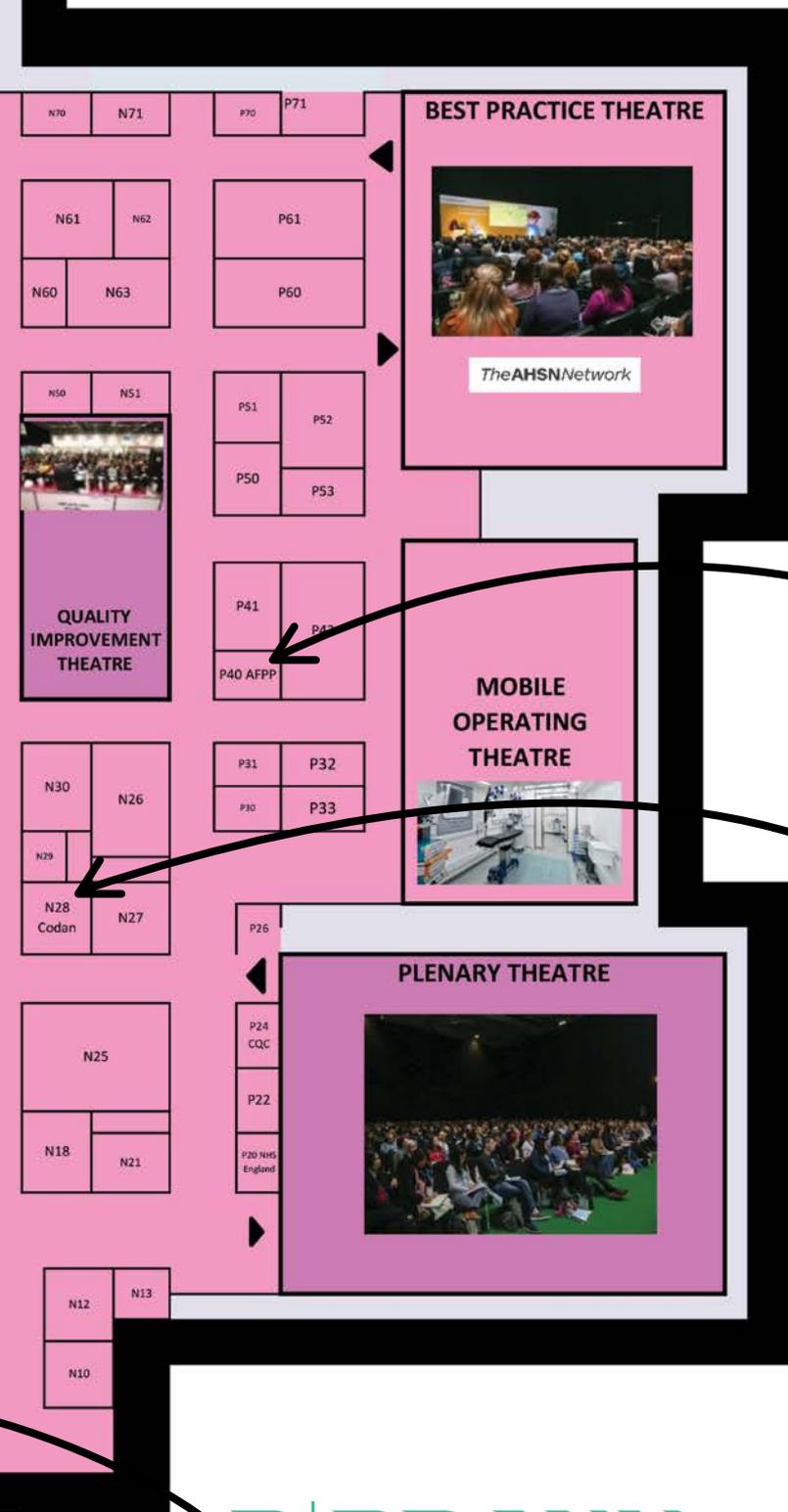
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