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

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# MDET

The Journal of Medical Device Education & Training

## The Power of Partnership

*NHS Improvement/ MHRA Conference*

## Surgical Smoke

## New EU Rules for Medical Devices

## Your Local NAMDET

## Voices:

*NHS European Office, NHS Improvement, MHRA, Science Council, AfPP*

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# THE DIFFICULT SECOND ALBUM

After the excellent feedback and reviews of the MDET journal launch in February, the editorial team are faced with the task of raising our standards and producing an exceptional second edition. Having researched 'Second', we need to ensure that we do not suffer the sophomore slump or sophomore jinx often referred to as an instance in which a second effort fails to live up to the standards of the first effort. Some might liken it to the 'difficult second album' concept for those that are aware of a celebrated music artist following a sure fire hit with a flop! We are though very hopeful that you feel we have filled the pages with extraordinary information, wonderful updates and upcoming events. The report from the excellent NHS Improvement and MHRA organised MDSO and MSO conference is a must read. Steve Veck challenges us about how safe we really are where surgical plume is involved. At a time when Britain's global citizenship is very much in the limelight you can read what amazing work some of our colleagues are doing to support developing countries through medical device initiatives. And as for the Selfie images of my dear colleagues - well I will let you decide that for yourselves!

In the months since our first MDET journal the NAMDET Management Board have been working busily to move the organisation's important agenda forward. Many of you will know that we are again presenting our Annual conference in Birmingham and have started to put the programme together using your suggestions for content and speakers. Conference title is still to be decided with more information available soon but, whether you are a member yet or not, please pencil the 2nd November into your diaries; it will be a conference worthy of your time.

NAMDET are also partnering a dedicated Medical Device conference programme at the Patient First Event taking part at Excel in London Docklands, also in November (21st and 22nd) This is an excellent opportunity, whoever you are, to come and meet and engage with NAMDET and our work. Members are invited to come and help out on our NAMDET stand and to present in the conference open theatre. More information on these events will be accessible, as it becomes available, on both the NAMDET website and the NAMDET Facebook pages

NAMDET are in discussion with AHCS (Academy for Healthcare Science) to take an active role in the manufacturer Representative Credentialing target setting and the education levels that will be required. As this progresses information will be shared through MDET including future contributions from AHCS.

Many of you will have seen that we are looking for members to join our new NAMDET Working Group and we have had some exceptional applications. The NAMDET Directors will be making decisions in early May and will be announcing the successful applicants on the NAMDET website and Facebook pages. The working group will be responsible for taking forward a number of projects to promote and support NAMDET and our 5 year plan.

Finally, we are initiating a technology update of our websites. The updates will include a new registration area, an updated members' area and additional security. We will also be developing the website to be mobile and iPad friendly to allow access from anywhere. At last I hear you cry! The MDDL and educational website will also be upgraded and we are in the late stages and very excited to be working toward a link with a major educational body to work together to develop new modules and update the e-learning that we have available already. I will update through these pages as soon as we have agreed the detail.

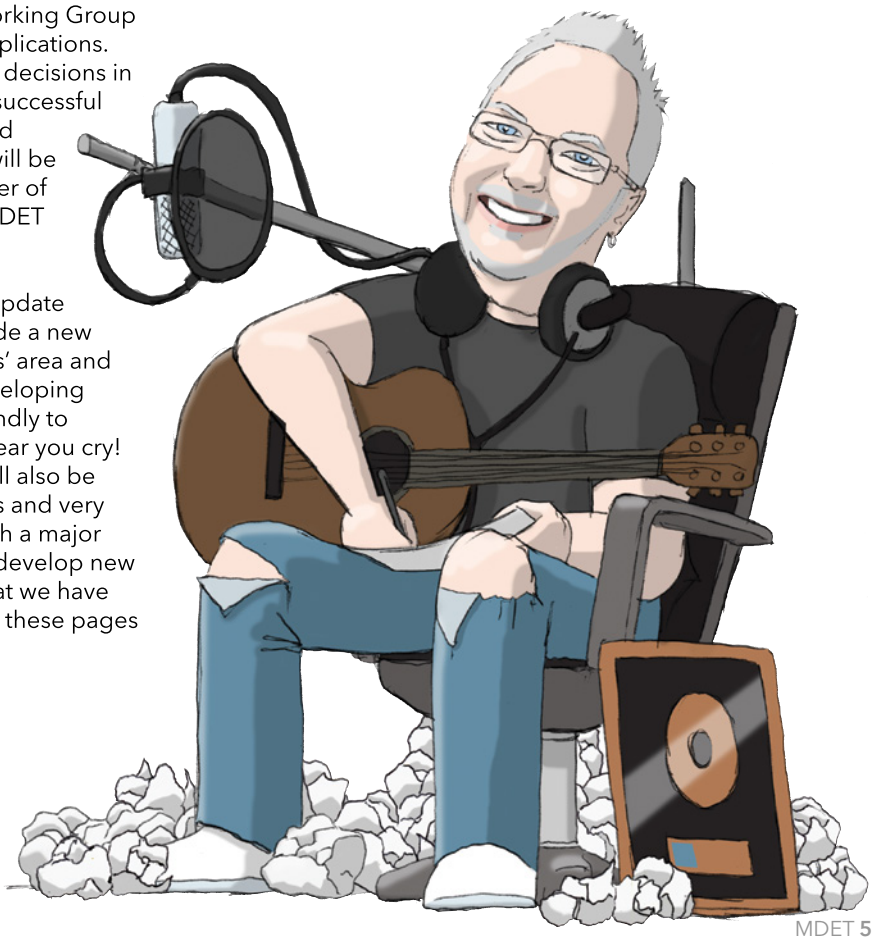
Very finally, NAMDET Directors have been trying to get to all of the regional meetings to meet members and ensure that the regions receive information directly. So, if you haven't seen us yet, we would hope to catch you in the next quarter.

*Any questions then drop any of us a line.*

*I hope that you continue to enjoy this issue.*

**Mike Peel**
NAMDET Editor and NAMDET Finance Director

Please do give us any feedback on the journal by emailing: editorial@mdetjournal.com We also invite you to contact us if you have a topic you would like to write about for MDET to publish. And if you are reading a digital version and would like to read a print version or vice versa, or if you want a colleague to get their own copy rather than steal yours, then the place to subscribe is: www.mdetjournal.com



SAFETY PARTNERS

Claire Read reports from the third NHS Improvement/MHRA conference for MDOs/MDSOs

# The power of partnerships

At times, the third national conference for medical safety officers (MSOs) and medical devices safety officers (MDSOs) sounded a bit like an episode of Blockbusters: lots of people enthusiastically asking for a 'p'. The word most frequently hiding behind that letter? Partnerships.

Addressing the potential patient safety risks of injectable phenytoin, Bev Curtis, Equipment Library Manager and MDSO at Harrogate and District NHS Foundation Trust, paused to ask her audience a couple of important questions. How many, she enquired, were medical device safety officers (MDSOs)? The majority of hands in the room shot up. The follow up question, however, received a significantly more muted response:

How many of the MDSOs in the audience knew who their organisation's medication safety officer (MSO) was?

A couple of delegates reported they worked closely with their MSO. Some knew the name of the relevant colleague. But many admitted the identity of the MSO remained a mystery.

## The need for collaboration

It was a state of affairs Ms Curtis suggested needed to change if patient safety alerts – including for injectable phenytoin – were to be reliably actioned.

Indeed, if there was one overarching theme to emerge from the third national conference for MSOs and MDSOs, it was the value of partnership working in bolstering patient safety. In opening the event – which took place in London in late January, and which was jointly organised by NHS Improvement and the Medicines & Healthcare products Regulatory Agency (MHRA) – Mike Durkin argued the collaborative approach represented by the conference was to be celebrated.

## Envy from elsewhere

*"The fact that these networks have been brought together is an incredible achievement,"* argued Dr Durkin, Director of Patient Safety at NHS Improvement. *"But the fact it's been sustained to have its third year with very little financial resource put into it, all really from the energies of [its members], is a real testament to you."*

He argued the networks were the envy of other nations. *"Other countries are looking at these networks and asking how this collaborative approach seems to keep on going, when other countries find it difficult to do."*

**Bev Curtis**
*Equipment Library Manager and MDSO at Harrogate and District NHS Foundation Trust*

**Dr. Mike Durkin**
*Director of Patient Safety at NHS Improvement*

**June Raine**
*Director of Vigilance and Risk Management of Medicines*

**Valerie Field**
*Devices Division at MHRA*

## A relentless commitment

Also provoking worldwide envy was the NHS's approach to publishing data on potential safety issues, and he argued here too partnership was central. *"A remorseless and relentless approach to publishing data is key, we think, to improving the quality of care that we offer our patients,"* Dr Durkin said.

*"This again is seen as an amazing achievement by the NHS when you go to other countries, who actually are fearful of publishing data on any outcomes for their care, unless it's within small research approaches and small studies – people are very wary about producing national data on the quality of care offered."*

He continued: *"It's an incredible achievement from those of you who are involved in the local systems that you've continued to work to make sure that all of this data is accumulated and packaged up and brought to the National Reporting and Learning System (NRLS)."*

## The value of local reporting

Without that local support, he said, there was simply no national progress. *"We are here because you're here, and we can't do any work at a national team level unless we have the knowledge and support and basis of information from what you provide. Local risk management systems are key inputs into all our information systems."*

Of course, the national focus on device and medication safety does not just come from NHS Improvement. It also comes from MHRA, and June Raine suggested the partnership between these two bodies must continue to evolve if risk management is to be effective. *"Our partnership with NHSI I think needs to move to almost consanguinity: we need to be joined at the hip, I think, because one should not be there without the other."*

## Devices and medicines unite

She also spoke of how collaborations within MHRA were being bolstered. *"Devices and medicines are aligning,"* reported Dr Raine, who is Director of Vigilance and Risk Management of Medicines. *"It's a no brainer that many of our approaches to detect, assess and manage risks are going to have commonalities. And best practice in both devices and medicines can build something really important and groundbreaking for the future."*

> patient safety is a team effort

Added Valerie Field, Devices Division at MHRA: *"The patient safety vigilance strategy [means] we're working much closer between devices and medicines to look at common points where we can streamline services to pick up signals, assess signals, and get out safety information and make things safer."*

It is the sort of pooling of knowledge which Ms Curtis said had been central to her trust managing the potential risks of injectable phenytoin. It was her MSO colleague who first received the November 2016 alert about the drug, which is an anti-seizure medication often used to stabilise patients experiencing life-threatening epileptic seizures.

## Leaning on and learning from one another

The alert speaks of risks in both use of the medication and use of the device to deliver the medication. *"So she forwarded it on to me as well, because it's about putting things in place to make sure the device is safe as well as the drug."*

Together, they have ensured that when IV phenytoin is delivered from the trust's pharmacy it comes with a giving set for the pump. This means the healthcare professional has no difficulty in finding the inline filter which must be used when the drug is given. There is also a clear warning label giving advice on both medicine and administration – for instance, it reminds how to calculate dose at the same time as reminding that the line must be flushed.

*"It's about building a network of the people that you need to work with,"* said Ms Curtis when talking about this approach. The speakers and attendees at the MDSO/MSO conference – national and local; medicines-focused or device-focused – all seemed to be in complete agreement.

# Reporting for duty

Standfirst: The value of reporting patient safety risks was frequently emphasised at the MSO/MDSO conference. But with it came an acknowledgment that changes are needed if the full value of such reports is to be realised.

**Professor Ann Blandford**
*Human-Computer Interaction and Director of the University College London Institute of Digital Health*

When Ann Blandford and her academic colleagues examined the free text fields in reports on infusion pump incidents, something stood out. *"We found a lot of them really hard to understand. I know we're not pharmacists, we're not clinical specialists, but we've been working in this area for quite a long time, and I think we should have been able to understand rather more than we did if they're to be useful more broadly."*

The Professor of Human-Computer Interaction and Director of the University College London Institute of Digital Health said problems included the use of abbreviations that might only make sense to one professional group, a lack of clarity over who had actually written the report, and the inclusion of many details that are highly specific to the local context.

## Lack of clarity

*"So when it moves into the national reporting system it is less comprehensible than it might have been within the local context of the hospital or the care environment for which it was originally written."*

The value of reporting medical devices and medications incidents – and near misses – has long been stressed. There was no change to that message. As Valerie Field put it: *"My plea is to please report to us."*

## Reporting increasing – with a caveat

Ms Field, of the Devices Division at MHRA, noted that while reports of adverse incidents relating to medical devices have grown steadily in recent years, that is mostly down to manufacturers. As a proportion, incidents reported by the NHS have remained fairly static since 2012. Ms Field emphasised: *"We act on numbers. So we need evidence from you as the MDSOs."*

Yet the conference also saw an acknowledgment that reporting isn't perfect, whether in the form of Professor Blandford's research or in Mike Durkin's admission the National Reporting and Learning System (NRLS) needs to evolve.

## Embracing a digital future

*"NRLS is a fine, fine process,"* Dr Durkin, director of patient safety at NHS Improvement, told delegates. *"But it's got to change, and we are determined to change it – to bring about a healthcare reporting system that is appropriate for the 21st century, that uses all the technologies and abilities that we have now in terms of our smartphones and various elements of media, but also that it opens itself up to being an appropriate vehicle for patients, for families and for others."*

That won't be an immediate change – it is intended the new system will be introduced in 2018. But June Raine pointed out that the move to embrace digital in incident reporting can already be seen in the Yellow Card app, launched in 2015. *"Not only can you send in reports very simply and very securely, but you can create a watchlist with products of interest and watch its safety profile as it involves,"* explained Ms Raine, Director of Vigilance and Risk Management of Medicines at MHRA.

## The need for system learning

For Professor Blandford, there would be real value in any new systems helping to bring out the system factors behind incidents as well as highlighting any organisational issues. *"As a human factors specialist, we believe patient safety takes place – and is managed within – a broader context,"* she explained.

**How might that broader context be teased out in reports? She referred back to the key theme of the conference: partnership.**

*"My intuition is that there's a huge value in not looking at each incident within your organisation in isolation, but to think why a particular incident happened based on your own local culture and practices – trying to build your own local triangles, if you like, about the underlying causes of each incident. And then perhaps having a way of reporting those insights on top of the individual incidents that gave rise to those insights.*

*"So you as an amazing group of people representing a large number of different organisations, I think it is about working together, having your own teams within your own organisations, and then coming together in events like this to share the understanding that gives you the systems-level learning and the organisational learning."*

# THE CODE FOR SAFETY

Iain Davidson, Chief Pharmacist and Chief Clinical Information Officer at Royal Cornwall Hospitals NHS Trust, had the apparently tricky challenge of "making barcodes sound sexy". But considering the enormous safety and efficiency benefits barcode scanning can offer to healthcare, it quickly becomes clear why it should be a priority.

In 2013, hundreds of beef products were withdrawn from supermarket shelves. Routine tests had uncovered the presence of horse meat, and action was taken which removed them from the market within hours – despite horse meat consumption not posing a threat to human health.

## The trouble with tracing devices

The previous year, a UK report found a problem with silicone breast implants made by French firm PIP. They had double the rupture rate of other implants, leaving women – including many breast cancer patients who had the implants as part of reconstructive surgery following mastectomy – at increased risk of silicone gel leaking into the body. Also that year, the MHRA issued updated advice on metal-on-metal hip replacements. These prostheses could wear down quickly in certain patients, it said, and patients be at risk of traces of metal leaking into the bloodstream.

Yet a full five years after these issues were discovered, there is still no way of knowing the identity of every UK patient who received a PIP breast implant or metal-on-metal hip replacement.

**Iain Davidson**
*Chief Pharmacist and Chief Clinical Information Officer at Royal Cornwall Hospitals NHS Trust*

**Lorna Wilkinson**
*Director of Nursing at Salisbury NHS Foundation Trust*

**"What we're trying to achieve through Scan4Safety is matching the right patient, right product, right place and right process around whatever intervention we're providing for that patient – the four Ps," explained Ms Wilkinson, who is Director of Nursing at Salisbury NHS Foundation Trust.**

## The four Ps

So why could retail track contaminated meat within hours yet healthcare cannot track problematic implants even after years? It all comes down to the apparently humble barcode. Prevalent in retail for years, it has never been consistently used within healthcare – and an inability to reliably track and recall products has been the result.

The MSO/MDSO conference heard from two speakers who are at the vanguard of trying to change that. Lorna Wilkinson and Iain Davidson each hail from Scan4Safety demonstrator sites. These six trusts, up and down the country, are exploring the benefits of using standardised barcoding called GS1.

The idea is that a barcode on the patient's wristband is scanned before any intervention. Scanned too are the barcodes on the products used, and the barcode of the staff member carrying out the intervention. In that way, complete traceability is provided.

## Total recall

Mr Davidson, Chief Pharmacist and Chief Clinical Information Officer at Royal Cornwall Hospitals NHS Trust, illustrated how such a process would change the recall of a drug. *"If we can get GS1 working, basically at the touch of a button you'll know if you've got any of the affected product coming in from your wholesaler, you can quarantine that when you receive it, you'll know exactly whether you've got the affected batch on your shelves, in your pharmacy, up on the ward, whether you've administered any of the affected batch to your patients, or whether you've sent any of that batch home. So it's a much quicker process, a much more robust and thorough process,"* he concluded.

And one which would, of course, apply equally to devices. Take the cardiac catheterisation labs at Salisbury NHS Foundation Trust, for instance. Ms Wilkinson explained any patient having a procedure there has their barcode scanned, and that every item used during the procedure is also scanned.

## Alerting staff

Not only would that make any subsequent safety recall of a product much simpler, it also leads to better stock management and greatly reduced risk of expired product being used. *"When you're scanning at point of use, it will alert staff to the fact a product is expired,"* said Ms Wilkinson.

Valerie Field, from the Devices Division at MHRA, suggested many previous safety issues with devices could have been addressed had barcode technology been used. She pointed to an incident of an uncontrolled bolus delivery with a syringe driver, in which it subsequently became clear the syringe used was not compatible. *"Maybe there if we'd had barcoding and scanning for safety, that would have alerted someone at that point that it wasn't right."*

## Taking action now

The six original Scan4Safety demonstrator sites will continue their work for another year, and there are hopes the programme may be extended to other sites. But Mr Davidson emphasised that any organisation can take action now to increase its use of barcodes.

*"What I think I'm asking of the community is start to look at your processes at the moment – are you utilising barcode scanning as much as you can? There are lots of systems that we've already got in place that have scanners and barcodes in there, but we don't necessarily utilise them."*

SCAN4SAFETY

# The safety paradox

NAMDET chair Paul Lee might reasonably have expected the introduction of new insulin safety needles to contribute to his organisation's safe use of sharps. But, as delegates at the MSO/MDSO conference heard, a safer device doesn't always mean it's safer for patients.

When the Health and Safety Executive (HSE) visited Abertawe Bro Morgannwg University Health Board in 2015, the result was a five page enforcement order on safe use of sharps. It isn't an unusual outcome. Of the 40 healthcare organisations HSE has inspected in the past year and a half, 45 per cent have received such notices. A striking 83 per cent of all inspected organisations were deemed not to be complying with regulations around the safe use of sharps, and nine out of 10 were deemed as having breached health and safety in some way.

**Paul Lee**
*Medical Device Training Manager at Abertawe Bro Morgannwg*

Paul Lee – Medical Device Training Manager at Abertawe Bro Morgannwg and currently on secondment to NHS Improvement as Patient Safety Lead for Medical Devices – told delegates of the extensive work which followed the enforcement notice.

*"We developed an interactive website, local safety notices and alert systems, and a 40 page brochure for all staff in the organisation. On one side are all the part numbers, and on the other the instructions from the manufacturer."*


## Why safer can mean less safe

The efforts meant that, on its next visit, the HSE fully rescinded the notice. But work on the safe use of sharps is continuous, and the introduction of new safety needles for administration of insulin has introduced a new challenge to the mix.

Safety-engineered insulin devices dramatically reduce the risk of needlestick injuries as, once the guard has been activated, it is impossible to make the needle come out again. However, if the device is not used correctly the patient does not receive the medication. And that can lead to a potentially life threatening outcome.

As Mr Lee, summarised: *"The patient always receives insulin with non-safety products, but there is the risk of sharps injuries. With safety products, you can guarantee you won't get stabbed, but you can't guarantee the patient will get insulin."*

## Balancing risk and benefit

Some delegates reported their organisations had actually stopped using the safety devices after incidents of patients not getting the correct dose of insulin. It is a perfect example of how an apparent increase in a device's safety can paradoxically create other safety risks.

Valerie Field, Devices Division at MHRA, recalled another: the heart valve manufacturer which decided to introduce a silver coating to its products. *"There is a small risk of endocarditis with [artificial heart valve] patients, and silver is known to combat infection in topical areas. Unfortunately, the silver inhibited the tissue growth needed to cover the implant and render it non-thrombogenic. So thrombotic complications and strokes increased.*

*"It was completely withdrawn, worldwide,"* she explained. *"But it's a salutary lesson, I think, in risk/benefit and making sure that every risk is investigated."* And in the value of the work of medical device safety officers.

# Surgical Smoke:

***Steve Veck, Electro Surgery Independent Consultant reviews the risks of surgical smoke in Electrosurgery and the perhaps worrying lack of appropriate national policy***

The modern operating theatre is often well equipped, with a wide range of modalities to cut or coagulate tissue. These can include Electrosurgery, Laser and Harmonic Scalpels. These devices are capable of providing cutting, coagulation, vaporisation and ablation of human tissue.

All of these modalities are undoubtedly beneficial in the surgical environment; however, none of these devices can be excluded from the production of surgical plumage. Indeed, with the increased application of Electrosurgery and Harmonic Scalpel in surgery, the issue of surgical smoke production is only exacerbated.

Smoke plumage contains 95% water vapour and 5% contaminates, which include chemicals with varying degrees of toxicity. Perhaps the most poignant of these is carbon monoxide (MO) along with acrylonitrile. Other chemicals, although in smaller quantities include formaldehyde, hydrogen cyanide and benzene. Significantly, benzene has been shown to be responsible for the mutagenicity of electrosurgical smoke.

The risks associated with Laser smoke plumage have been readily accepted and appropriate policies established to remove such smoke by surgical smoke evacuation systems (figure 1).[1,2]

## Surgical Smoke in Electrosurgery

Despite the widespread use of Electrosurgery, over a considerably historic period, few provisions have been made to protect staff from the risks of the associated surgical smoke.

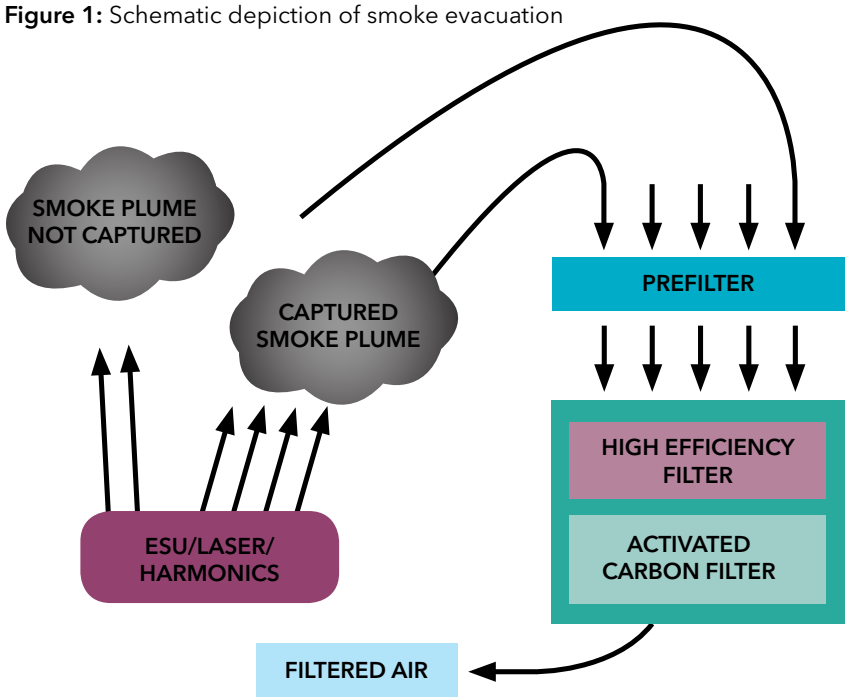
Research by Ott (1993) has shown that surgical smoke is hazardous to the surgical team who may be exposed day after day.[3] The concerns that make plume and inhalation a problem include: odour, particulate matter, size and potential viability of the actual smoke.[4]

Even with airflow in theatres, the smoke plumage continues to circulate in the area.

Surgical smoke has been described as having biological and chemical hazards and each has its individual risks. Biological contaminants can consist of carbonised tissue, blood, infectious viruses and bacteria.

The second group of contaminants are chemicals. These are toxins, which are present in the gases and create an acrid smell commonly associated with electrosurgical procedures and burning tissue. There have been over 40 chemicals identified in surgical smoke so far (Figure 2).[5]

**Figure 1:** Schematic depiction of smoke evacuation



# The Risks

**Figure 2:** Examples of chemicals identified in surgical smoke

| | | |
|---|---|---|
| Acetonitrile | 2,3 Dihydro indene | 6-Methyl indole |
| Acetylene | Ethane | 4- Methyl phenol |
| Acrolein | Ethene | 2-Methyl propanol |
| Acrylonitrile | Ethyl benzene | Methyl pyrazine |
| Alkyl benzenes | Ethylene | Phenol |
| Benzaldehyde | Ethynyl benzene | Polyromatic hydrocarbons |
| Benzene | Formaldehyde | Propene |
| Benzonitrile | Furfural | Propylene |
| Butadiene | Hexadecanoic acid | 2- Propylene nitrile |
| Butene | Hydrogen cyanide | Pyradine |
| 3-Butenenitrile | Indole | Pyrrole |
| Carbon disulphide | Isobutene | Styrene |
| Carbon monoxide | Methane | Toluene |
| Creosols | 3- Methyl butenal | 1 – Undecene |
| 1- Decene | 2- Methyl furan | Xylene |

Particulate matter poses a potential hazard as the smallest particle matter that can be seen is 20 microns. Unfortunately, surgical masks only provide minimal protection.

Gatti et al (1992) suggests that surgical masks are unable to filter particulate matter less than 5 microns.[6] This raises concerns when studies indicate that Electrosurgery can produce an aerosol with particulate matter less than 5 microns. In fact, Ball (1996) advises that approximately 77% of particulate matter is less than 1.1 microns.[7] Similarly, lung damaging dust ranges from 0.5 – 5 microns.

Where particles are concerned, viruses seem to be the biggest hazard, as they range from 0.3–0.02 microns, making them small enough to pass through a general style surgical mask and be inhaled.[8]

## Risks of surgical smoke ingestion

The following list depicts health risks associated with ingestion of surgical smoke:

- **Airway Inflammation**
- **Hypoxia / Dizziness**
- **Coughing**
- **Headaches**
- **Tearing**
- **Nausea / Vomiting**
- **Hepatitis**
- **Asthma**
- **Pulmonary Congestion**
- **Chronic Bronchitis**
- **Carcinoma**
- **Emphysema**
- **HIV/AIDS**

Certain HPV types that infect the genital region preferentially have been found in a majority of cervical carcinomas and in a few laryngeal malignancies, suggesting the risk of HPV DNA exposure.

As mentioned earlier, it has also been proposed that benzene is significantly responsible for the mutagenicity of electrosurgical smoke.[9]

One study also pointed out that partial viral or oncogene sequences can pose a significant health hazard for exposed personnel since they may have transforming potential.[10] This study also demonstrated reduced risk the further from the point of smoke production.[10]

## Conclusion

The risks of surgical smoke inhalation have been well reported and documented, through a wealth of scientific data. With greater use of Electrosurgery and Harmonic Scalpels as an interventional tool, the levels of risk with regard to surgical smoke plume will inevitably increase.

With this evidence many countries have adopted mandatory policies, in order to provide protection for personnel in the areas at risk.

However, to date there is no mandatory policy from the Department of Health within the UK and Ireland. Neither does there appear to be any recommendations or suggestions with regards to providing protection. With the current emphasis on Health and Safety in the workplace, it seems bizarre that this significant risk has been ignored.

Surgical Plume is ideally removed by a dedicated Surgical Smoke Plume Evacuator. There are many commercial medical companies offering a wide range of such generators, some in combination with an Electrosurgical Generator.

A stand-alone unit would cost in the region of between £2,500 - £6,000. In general terms there are also a multitude of accessories, both single use and reusable. They include, applications in Open, Laparoscopy and Colposcopy settings. These devices can be purchased for as little as a few pounds each.

From the risk analysis standpoint, the cost of providing efficient protection is at best, minimal, compared to the potential outcomes. The cost of not providing personnel adequate protection is yet to be realised.

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# Medication management: medication safety from pharmacy to bedside

**Expert pharmacists from around Europe discussed the role of technology in medication management from prescription to bedside administration at the Becton Dickinson (BD) satellite symposium held at the 21st European Association of Hospital Pharmacists (EAHP) Congress. This report was originally published in Hospital Pharmacy Europe.**

The speakers covered the rationale for introducing new technologies, implementation and evaluation to improve medication safety.

## How improving the quality of medication management helps reduce medication errors

Hospital pharmacists must have a strategic vision for the implementation of new technologies in the process of medication management, Professor Pascal Bonnabry, Chief Pharmacist at Geneva University Hospitals, told symposium delegates. Hospital pharmacists have a key role in implementing solutions to improve the safety, efficiency and traceability of drug use.

It is important to understand the mechanisms behind the errors that occur in getting medicines to the patient. An error reaching the patient involves two errors – one in the action, for example, selecting the wrong drug, and one in the control, for example, failing in the double-checking.

Understanding this mechanism is very important because when implementing new technology, you have to look at both the action and the controls that are built into the system, to reduce the frequency of errors and increase the reliability of controls.

A simulation study of dispensing errors by nurses showed an error rate of 3% and the majority of errors found were drug selection mistakes. Given the number of drugs dispensed in hospitals every day, this is a lot of errors that can potentially harm patients. Controls and double-checks work around 85% of the time but they are not a magic bullet, he said.

## Human error

Many high-risk activities in hospitals are based on human reliability. Humans are not perfect, but in hospital, where patients' lives are at risk, it is a problem not to be perfect. The science of ergonomics can help pharmacists make their processes safer and the following are tips that can help overcome problems of human error in processes:

- Avoid reliance on memory
- Simplification
- Standardisation
- Use of constraints and forcing functions
- Use of protocols and checklists
- Information access
- Reduce handoffs
- Increase feedback.

Looking at these principles, he believes there is clearly a role for IT and automation.

## Implementation strategy

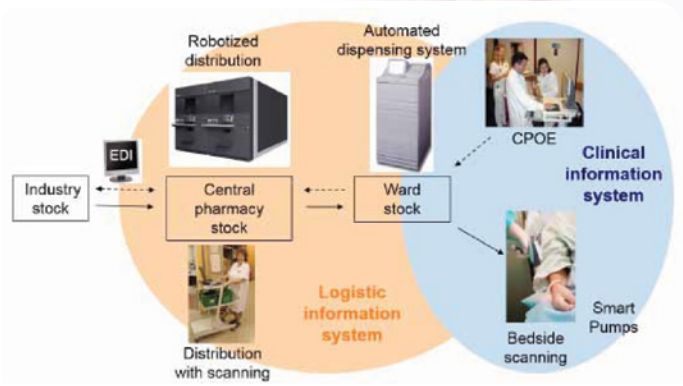
The importance for hospitals to have a strategy that defines what it wants to do in terms of its medication management, and how it will implement new technologies into its processes in the future, was emphasised and this should be regardless of the current organisational process.

He showed the 'roadmap' developed at the Geneva Hospital (Figure 1), which outlines the technological innovations it plans to introduce over time. Once you have a plan, you can set about implementing it against background constraints like budgets that don't allow you to have everything by tomorrow, he said.

The Geneva Hospital has robotised distribution with scanning, implemented full computerised physician order entry in the ward, and has started to implement dispensing cabinets. Smart pumps have been introduced in the neonatal intensive care unit and paediatric intensive care unit (PICU), and the hospital has introduced bedside scanning for cytotoxic drugs.

An evaluation of robotised distribution in the Geneva Hospital showed the error rate when drugs were being picked anually was around 1%, but that after robotisation was introduced this

Figure 1: 'Roadmap' developed at Geneva Hospital




fell to 0.5%. After working with the manufacturer to iron out problems, the error rate fell further to 0.13%.

Demonstrating improvements in efficiency and showing a return on investment was an important part of the evaluation. With manual distribution, technicians at the Geneva Hospital were picking 300 items an hour, but this rate nearly trebled to 860 after robotisation was introduced. Effectively, one technician looking after the robot can do the job of three technicians picking packages by hand. It was pointed out that an increase in efficiency makes financial directors happy.

Dispensing errors were reduced by a factor of ten following the introduction of automatic dispensing cabinets, and selection errors completely disappeared because drugs were stored in secure drawers.

**Professor Bonnabry summarised his key messages:**

- Automation and robotisation are important strategies to optimise drug management
- Safety, efficiency and traceability can be improved through use of these technologies
- Implementation must be planned and conducted by a multidisciplinary team
- These projects are challenging and must be led by a competent team with the time to do the job
- A strategic vision is essential
- The selection of the right partner to automate is essential

## Achieving high levels of quality and safety in IV compounding

A gravimetric IV preparation system can improve accuracy and help avoid errors of overdosing or under-dosing that put patients at risk, Dr Robert Terkola told symposium delegates. Clinical Assistant Professor at the University of Florida, President of the Austrian Society of Oncology Pharmacy and CEO at Health-Concepts E.U., Dr Terkola discussed preliminary findings from a study he was conducting with other centres around Europe to look at how a gravimetric system could improve safety in the compounding of cytotoxic drugs.

The GPP (Good Preparation Practice) study is a retrospective review of data gathered since the introduction of a medication workflow solution system in 10 European centres.

The study analysed the accuracy of the compounding of 1.2 million unique preparations using this software system, which supports IV compounding in the pharmacy. The system uses real-time gravimetric and barcode verification together with an onscreen guidance system to take the technician step-by-step through the compounding process.

As part of the comprehensive analysis of data provided by this workflow software solution, the study looked at error rates in the data overall, both by centre and by the > 200 individual operators. These 'errors' are not errors that reach the patient, but attempts at preparing the correct formulation that are picked up by the system and prompt the operator to adjust the compounding. Data from centres showed that just under 10% of preparation attempts were incorrect, that is, outside of the tolerance ranges set by the centres, with figures ranging from 5–16%.

## Individual drugs and accuracy

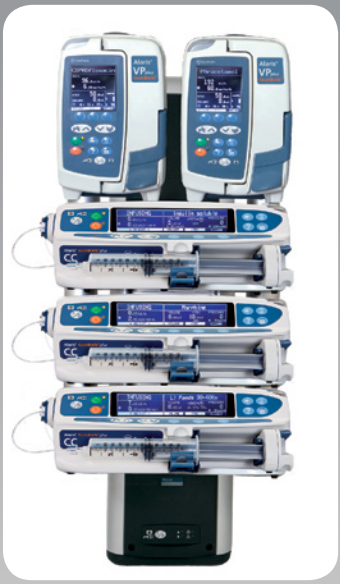
Data analysis showed that some drugs had a much higher error rate than others, with three drugs having preparation error rates over 50%. This information could be used to encourage the development of better formulations.

These preliminary findings showed that as the number of compounds prepared by a centre using an advanced gravimetric system increases so does the accuracy of the preparations. This supported the idea of encouraging technicians to stay in post rather than moving on, and he said this is sometimes advocated.

This gravimetric preparation system can improve accuracy and help avoid the errors of overdosing or under-dosing that put patients undergoing anticancer treatment at risk of toxicity or lack of effect. He explained how the use of a gravimetric system enables the identification and correction of potential errors.

The study also identified a range of drugs that are poorly formulated and make accurate dispensing difficult. It is to be hoped that new formulations of these drugs will be developed, allowing safer use, he concluded.

## Infusion medication safety at the bedside: experience in paediatric care



Smart infusion pumps are effective in detecting and quantifying programming errors and preventing them reaching the patient, pharmacist Dr Silvia Manrique- Rodríguez told symposium delegates. The hospital where she works, the Hospital General Universitario Gregorio Marañón in Madrid, has spent the last six years implementing smart pump technology in its PICU and had analysed its effectiveness and economic benefits.

The pharmacy at the hospital manages eight million drug administrations a year and has always employed new technology to help in processes around the prescription and administration of drugs. As well as decreasing the likelihood of errors, the hospital believes new technologies free its pharmacists to spend more time providing patient care.

The hospital has 100% electronic prescriptions (EPS) in both inpatient and outpatient settings. Currently, 54 automatic dispensing systems are connected to the EPS, and there are four dispensing carousels in the central pharmacy and smart pumps in critical care units. In addition, electronic administration records (eMAR) and barcode administration for chemotherapy are being implemented.

The hospital is implementing the use of smart pumps on a step-by-step basis, starting with paediatric intensive care due to the high risks associated with the administration of IV drugs in this setting.

Smart infusion pumps incorporate safety software and a drug library that lists maximum and minimum rates of infusion. When the infusion rate of a drug is set outside of these pre-set limits, an alarm is activated, which prompts the person responsible to check the rate they have selected is correct.

These integrated features mean smart pumps can significantly improve the safety of IV infusions, as although they do not prevent programming errors, they prevent them reaching the patient, she said.

A multidisciplinary team including doctors, nurses, pharmacists, technicians and IT specialists were involved at every stage of the implementation process, from the development of the drug library in the early stages through to analysing data reports from the smart pump systems.

### Error detection

Analysis of data from the smart pump systems showed that 10% of infusions programmed with the pump were started without using the drug library. This means that there was a 90% compliance with the safety software because 90% of all the infusions programmed with the pump were started through the drug library. And this percentage of compliance has remained constant over these years.

Over the five years since the system was implemented, 283 programming errors have been intercepted, with 58% of intercepted errors involving high-risk drugs. Example errors intercepted included an infusion of thiopental initially programmed for 18mg/kg/h and corrected to 8mg/kg/h, the upper limit for that drug; and an initial programming for insulin 75-times higher than the maximum limit. Further examples are shown in Table 1.

Having demonstrated the beneficial effect on safety in the hospital, the cost-effectiveness of implementing smart pump technology was assessed. A group of doctors and pharmacists examined the severity and likelihood of an adverse event from the first 92 prevented errors identified. 50% were classified as serious and 50% as having a high probability of causing an adverse event. Using a Spanish Ministry of Health guideline on the estimated cost of an adverse event being €6186, it was calculated that the hospital saved €160,092 in the first 18 months of implementation.

**Table 1: Some of the infusion programming errors prevented by the smart pumps and the upper limits for those drugs in the drug library**

| Drug | Upper limit | Initial program | Final program |
|---|---|---|---|
| Alteplase | 0.66mg/kg/h | 1.6mg/kg/h | 0.6mg/kg/h |
| Thiopental | 8mg/kg/h | 18mg/kg/h | 8mg/kg/h |
| Amiodarone | Loading dose 5mg/kg (15 min) | 50mg/kg | Infusion cancelled |
| Vecuronium | 0.2mg/kg/h | 0.6mg/kg/h | 0.2mg/kg/h |
| KCL | 1 mEq/kg/h (<20kg) | 2.3 mEq/kg/h | 0.3 mEq/kg/h |
| Insulin | 0.2 U/kg/h | 15 U/kg/h | 0.2 U/kg/h |
| Levosimendan | 0.2mcg/kg/min | 0.9mcg/kg/min | 0.1mcg/kg/min |

For every Euro spent on the technology, there was a return of two Euros. There were limitations to the estimates but the analysis provided a good idea of the scale of potential savings to the hospital, she said. The effectiveness of the smart pump system is dependent on user compliance with the safety software, which requires ongoing training and communication with staff. It is also necessary to keep the drug library updated and to ensure that all the pumps have the most recent version. Over the last year the hospital had been piloting a communication platform that significantly improved this process, allowing the pumps' drug libraries to be updated in real time and to be located in the ward. This platform also enabled continuous collections of data from the pumps, allowing the team to have regular analysis of the data and thus improving their infusion practice and clinical workflow.

## Integration is essential

It is important to be aware that when standalone smart pumps are used it is only the dose administered that can be guaranteed. It could still be the wrong patient, the wrong drug, the wrong route and at the wrong time. She suggested the solution is technology integration, having all the tools – electronic prescriptions, automatic dispensing, barcode scanning and smart pumps – working together.

The future will be to have prescriptions validated by pharmacies, with a nurse with a barcode reader checking the identity of the patient, the type of medication and the dose, route and time. She predicted once everything is checked, the infusion would start automatically from the pump rather than having to be programmed manually. In summary, smart pumps had been effective in detecting, quantifying and preventing programming errors reaching the patient in the hospital.

> *"The data obtained from the smart pumps has allowed us to make improvements in our clinical settings and reinforced good clinical practice," she concluded.*

## Conclusions

Summing up, the presenters highlighted the most significant challenges around implementing new technologies in the hospital. Commitment to the project is really important, Dr Manrique-Rodríguez told delegates. You have to be really convinced about the potential benefits of what you are doing and be able to transmit that enthusiasm to your colleagues.

> *"Secondly, good team working is essential because you can't implement a significant new system on your own."*

For Dr Terkola, it is getting the interfaces with other professions right to ensure smooth transitions of activity and responsibility between them. Integration of the systems, and the staff working with them is also key, he said.

Selecting the right technology company is important because you will be with that company for a long time, Professor Bonnabry said. And process organisation is key. When implementing new technologies you have to redesign the whole system. You have to take the opportunity to introduce new ideas and improvements. Work with people who know how to re-engineer processes, he said. Before closing the debate, he told delegates not to re-invent the wheel and advised that they talk to colleagues and visit hospitals that had implemented new technologies.

***"We have to improve the safety and efficiency of medicines delivery and new technology is the way forward,"***

*concluded Professor Bonnabry.*

# NAMDET regions

## NAMDET Scotland

NAMDET has a small group of committed individuals in Scotland, but as the Scottish Health Service works in a different way to below the border we need to work with Senior Management and their Medical Device technicians who are involved in the device education and training in the hospitals within the regions. If you would like to get involved, please contact Information@namdet.org for local information.

## Northern Ireland and Eire

Both NI and in Eire have NAMDET members and we would like to see if we can introduce a joint group across both areas. Again, if you would like more information then please contact Information@namdet.org for our help and support.


## NAMDET Wales

NAMDET (Wales) was formed in July 2014, with 24 members from Industry and various Health Boards. Since our initial meeting we have met on 4 other occasions. We have over 45 members who have express an interest in attending the meetings over the years but with the same loyal core members attending. Membership is not restricted to Welsh members, if you live close to the border and our group is the closest feel free to contact me for any details.

Following the initial meeting the Chair and Secretary were elected. The agenda was constructed with just 4 agenda points. As the meetings developed so did the agenda. It became apparent that all the NAMDET regions, with a slight variant are talking about the same agenda. In the Nov 2016 Board meeting it was decided to devise the top ten topics that were common to all.

For the next regional meeting our agenda will be switching focus to these top ten topics, with our group focusing on the topics our region has been allocating and updating the group with the feedback from the other topics.

We will aim to invite a guest speaker from industry, NHS or Government to present on a relevant topic that has been chosen in the previous meeting.

Rob Matthews chairs NAMDET (Wales) and he can be contacted at Robert.Matthews@wales.nhs.uk

## NAMDET South West

The SW Group meets quarterly, usually in Plymouth which is the most central location. Our group currently consist of Royal Cornwall Hospital, Plymouth Hospital, Torbay and South Devon Trust., Royal Devon and Exeter and North Devon Healthcare. New members are always welcome. We are currently working on a joint project to produce bite size videos which can be accessed through various technologies e.g. barcodes/QR code and potentially RFID tagging. The objective of this project is to support competency assessed nurses to maintain competency; with bite size reminders for using particular high risk device. So far, we have produced a support video for T34 palliative care pump. We have identified other infusion devices that are common across the SW which will be shared within the network. We hope this will encourage other Trusts to join us in developing these videos to create a national library for all to share. Royal Cornwall Hospital is in the process of introducing RFID tagging for medical devices so watch this space to how we can improve the utilisation of assets and improve patient care.

Contacts: Janine Webster, Chair: Janine.webster@nhs.net and Elizabeth Anderson, Co-chair: elizabeth.anderson14@nhs.net

## NAMDET London and the South East

There are approximately 125 NAMDET members from a variety of different organisations in this group. The membership has continued to grow rapidly and members include medical device trainers, EBME staff company trainers, company representatives, staff from acute and community NHS Trusts and the private sector.

Meetings are held three times a year and members are encouraged to attend the Annual Conference. Regional meetings are well attended and the group is always enthusiastic and committed to sharing best practice across the medical device network. Many of the group have become friends and we welcome members and

## NAMDET North East

NAMDET North East is a newly formed group which began in January 2017 and is chaired by Gill Hart from Newcastle Hospitals, with Christine Maddox from Northumbria Healthcare as secretary.

The North East group covers a large geographical area with members representing acute Trusts spanning from Durham and Darlington in the South, to Northumbria in the North and West; Sunderland, South-Tyneside, Newcastle and Gateshead sit centrally. There is also representation from Northumberland, Tyne and Wear Mental Health Trust which encompasses a geographical span from Sunderland to the Scottish Borders.

The group plans to work on 'hot' national topics, local topics and best practice sharing using a task and finish approach. The group members have a variety of backgrounds and roles within medical devices both within the NHS and Healthcare Industry; all members are expected to be active participants.

Contact NAMDET North East at **Christine.Maddox2@northumbria-healthcare.nhs.uk**

## NAMDET Yorkshire

Ey-up from us in Yorkshire! As the biggest county in the country, we are extremely proud to maintain a high profile within NAMDET.

NAMDET Yorkshire, with Bev Curtis as its Chairperson, currently has 70 members, made up of medical device trainers, EBME staff and company reps. We cover a large area across Yorkshire, Humberside and the North-East of England. Although we have recently lost some of our North-East members to their own, breakaway group. At the present time we have NAMDET Yorkshire members in 19 differing Trusts across our region.

We meet on a quarterly basis at varying venues across our area and try to meet with our colleagues in the North-West at least once in that time.

In the past couple of years we have focussed on the core objectives from the national plan, to try and increase awareness of NAMDET – we recently produced an A5 leaflet for our members to give to colleagues. At every meeting we have a conversation around incidents and often e-mail relevant information across members in between meetings as well. Recently we have discussed the problems with training staff whose first language is not English and the associated difficulties with translating complicated training information into the correct phrase in another language (Google Translate is often helpful, but not always accurate!)

Our corporate colleagues play an important role in our group and have been keen to look at the credentialing systems being developed nationally.

In the next 12 months we have agreed to look at the role of the key trainer, specifically around accountability and delegation. We delight in welcoming new members, or visitors from other regions at any time.

*Sitha later Pal!* ☺

Contact NAMDET Yorkshire at **BEVERLEY.CURTIS@hdft.nhs.uk**

non-members from other parts of the country to attend.

In March we were delighted to invite Andrew Davies from ABHI and Lisa Crowie from NHS England to give an update on the credentialing register and how a single set of policies could be nationally adopted. The implementation will require collaboration between Trusts, Industry and the Department of Health and the group is keen to support this initiative as it progresses.

The group are now looking to explore standardisation of training materials and national competencies and hope to link into the main NAMDET work-stream.

One advantage of our location is the proximity to London's ExCel which will be hosting the Patient First Conference on 21st and 22nd November. Our members will be very present on the NAMDET stand J50 to discuss the opportunities that NAMDET membership offers.

For more information on NAMDET London and South East contact **Mary.Caddies@bartshealth.nhs.uk**

## NAMDET West Midlands

The NAMDET West Midlands group was formed as a supportive and productive network to enable us to share information, opportunities and resources.

Our first meeting took place in November 2016 and we have recently held our second in March. A third meeting is planned for October 2017.

Our membership is comprised of Educators, EBME and Equipment Resource Library staff representing Heart of England, University Hospital Birmingham, Birmingham Children's Hospital, Leicester Hospital, Marie Curie Hospice Solihull, Birmingham Women's Hospital, Burton, Nottingham, Wolverhampton, George Elliot, and Shrewsbury & Telford. In addition, our meetings are also attended and sponsored by medical device company representatives.

As a new group, we have yet to establish working projects, but our meetings have discussed issues such as product liability, formation of equipment libraries, learner management systems, and drug error reduction software.

Anyone interested in joining our group can contact our chairperson, Beth Flint at **elizabeth.flint@heartofengland.nhs.uk** or **rebecca.delpino@heartofengland.nhs.uk**

## NHS European Office

# Medical Devices

**Sarah Collen**
*Senior Policy Manager - NHS European Office*

**On 5 April 2017 the European Parliament approved new EU rules on medical devices, concluding the EU process of negotiations on these new EU laws, originally proposed by the European Commission in 2012.**

The final adopted texts are expected to be published in the Official Journal of the European Union in May. In the meantime, you can read the text of the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation as voted by the European Council and the EU Parliament via our website **http://www.nhsconfed.org/regions-and-eu/nhs-european-office/influencing-eu-policy/medical-devices**

### Key changes the new EU rules bring include:

- Stricter requirements for notified bodies, stronger pre-market scrutiny and post-marketing surveillance: the surveillance of notified bodies by national authorities will be tightened. Notified bodies will have the right and obligation to carry out unannounced factory inspections, and they will have to employ medically skilled personnel.

Provisions will be laid down on manufacturers' responsibilities for following up the quality, performance and safety of marketed devices, including responsibilities for liability in the event of damage caused by a defective device and on registering complaints. The availability of data will be strengthened.

- Strengthened rules for high-risk devices and certain other categories of devices: before being placed on the market, high-risk devices may undergo an additional assessment from expert panels. The new provisions will also cover medical devices without an intended medical purpose, but with similar characteristics to medical devices (for example, fillers and coloured contact lenses for cosmetic purposes). Special requirements for manufacturers and notified bodies will apply in the case of devices that contain endocrine disruptors (ECDs) or carcinogenic, mutagenic, and reprotoxic (CMR) substances.

- Increased transparency and traceability: a central database will be set up, which will cover economic operators, notified bodies, market surveillance, vigilance, clinical investigations and certificates. In addition, it will provide patients, healthcare professionals and the public with comprehensive information on products available in the EU. Devices will have unique identification to facilitate traceability throughout the supply chain up to the patient/user. Furthermore, patients implanted with a device will be provided with essential product information ('implant card'), including any necessary precautions. In the field of IVDs, patients will have to be informed about the consequences of DNA tests performed.

### Relevance for the NHS

NHS organisations often produce diagnostic tests in-house or modify commercial kits to conduct essential specialised tests for specific groups of patients. They also modify or produce medical devices, such as software for MRI scanners and devices for use on special groups of patients (for example, infants and children). These practices allow the NHS to provide state-of-the-art healthcare to patient groups needing specialised care, to respond rapidly to new or emerging threats, and to promote the development of more innovative solutions through collaboration by medical researchers with peers.

The original proposals for new EU legislation seriously threatened the ability of NHS hospitals to continue to modify or produce diagnostic tests and medical devices 'in house'. The proposed restrictions could have resulted in negative implications for patients, such as:

- Delays in providing healthcare, with turnaround time for new industry manufactured devices for novel and/or emerging diseases significantly longer than those produced 'in-house';

- Lack of available CE marked tests and devices for certain conditions or groups of patients. Test devices for certain rare genetic and infectious diseases are not available on the market, and devices for rare conditions may not be manufactured where no commercial incentive exists; consequently, there could have been implications in terms of the ability to carry out some diagnostic tests for certain patient groups in the future;

- Lack of devices modified to make appropriate and safer for use on certain populations, for instance, for use with infants and children.

The NHS European Office engaged extensively throughout the EU process, informing EU decision-makers of possible consequences of their proposals and suggesting changes in the interest of the NHS. Thanks to our influencing work, EU decision-makers recognised the need to ensure that hospitals can continue to produce devices and diagnostic tests 'in house' in the future, while ensuring that their quality and safety is guaranteed by light touch provisions.

NHS Improvement

VOICES

# Patient Safety

**Frances Wood**
*Head of Patient Safety - Review and Response*

Learning from patient safety incidents is key to understanding and making improvements in patient safety. Every single incident that is reported could help protect patients from harm.

NHS Improvement's National Patient Safety team is responsible for the National Reporting and Learning System (NRLS) and the review of the incidents it records. The NRLS provides vital insight into patient safety in the NHS, and is particularly used to spot new or under recognised issues that could require national action.

In 2016, almost 2 million incidents were recorded in the NRLS, mostly via local risk management systems. This number continues to grow thanks to the efforts of NHS staff, making the NRLS the world's largest patient safety reporting system, accumulating over 15 million reports since its launch in 2003. Such a large collection of incidents provides a unique capacity to identify and understand infrequently occurring patient safety risks which are unlikely to be characterised at a hospital or local level. This includes early warnings of the inevitable yet unforeseen new risks associated with changes in healthcare practices and the introduction of new technologies.

The NRLS is also a repository of data that allows for mining of issues affecting patient safety. This can often uncover multiple factors only identified by reading multiple reports on similar issues. Therefore all incidents, not just those resulting in severe harm or death, support learning.

The patient safety team's multi-disciplinary clinical review function advises and manages this risk surveillance, review and response process. 'Reading the words' not merely 'counting the numbers' provides invaluable information on the nature and scale of harm reported. The team review around 20,000 incidents each year, including all reported as resulting in severe harm or death.

## Stages of review and response

**1.** Surveillance/vigilance: Incident reports graded by reporting organisations as severe harm or death are reviewed weekly by the NHS Improvement patient safety team.

**2.** Incident categorisation: Incidents are grouped by type (themed).

**3.** Issue identification: An incident is identified as a 'trigger' for potential national response.

**4.** NRLS scoping: Multispecialty discussion and agreement for deep dive into NRLS pool (this will include looking at reports graded at lower levels of reported harm/ no harm reports).

**5.** Review of findings: Multispecialty review and discussion.

**6.** Response: Level and nature of response agreed in consultation with other stakeholders, including patient representatives.

The majority of death and severe harm incidents are not new or under-recognised but are patient safety issues known to be complex requiring cross-system improvement work. Examples include suicide prevention, inpatient falls, pressure ulcers, delays in diagnosis and medication error. This information is shared with partners, such as the Patient Safety Collaboratives, already working to address those risks.

Where an issue meets the criteria for national action, it is presented for discussion at the National Patient Safety Response and Advisory Panel. The panel provides expert insight and advice and its representatives include professional bodies, patient groups, staff, academics, arms-length bodies and regulators, amongst others.

The resulting national action commonly takes the form of a Patient Safety Alert, however other options such as working with Royal Colleges are also explored.

Since the National Patient Safety Alerting System was launched in December 2013, 45 alerts have been issued to date. There are three types of alert; 'Warning' – typically issued to raise awareness of a new or under-recognised patient safety issue; 'Resource' - to ensure healthcare providers are made aware of and implement any substantial new resources that will help improve patient safety; and 'Directive' – where a specific, defined action to reduce harm has been developed and tested to the point where it can be universally adopted.

### Patient Safety Alerts related to medical devices

- Risk of severe harm and death due to withdrawing insulin from pen devices
- Reducing the risk of oxygen tubing being connected to air flowmeters
- Risk of using different airway humidification devices simultaneously
- Risk of death and serious harm by falling from hoists
- Managing risks during the transition period to new ISO connectors for medical devices
- Risk of severe harm and death from unintentional interruption of non-invasive ventilation
- Risk of inadvertently cutting in-line (closed) suction catheters
- Risk of using vacuum and suction drains when not clinically indicated
- Improving medical device incident reporting and learning
- Risk of associating ECG records with wrong patients
- Placement devices for nasogastric tube insertion DO NOT replace initial position checks
- Risk of hypothermia for patients on continuous renal replacement therapy
- Non-Luer spinal (intrathecal) devices for chemotherapy

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# Patient Safety.
# Together, we'll make it better

**New for 2017, working in association with the National Association of Medical Device Trainers and Educators (NAMDET), this show floor education feature will cover best practice, safety and procurement and provide invaluable content and networking for medical device safety officers, medicines safety officers and representatives from the medical equipment groups within hospitals.**

Topics include:

- **How can NAMDET help you with your company and business going forward?**
  Background and History of NAMDET and why you need to know more.
- **Can e-Learning and self declaration really be safe?**
  Insight into the new MDDL e-Learning and Birmingham University Hospital CPDs
- **How to avoid Legalities around Medical devices and bad judgement.**
  Do you know the law and how it affects you and your staff?
- **Micro and Leur connectors. Most common issues and how to help eradicate them**
  Do you and your staff have issues with connectors?
- **Manufacturer Rep Credentialing. The latest information.**
  How will this affect manufacturers and Trusts
- **Infusion Pumps - Common Errors and how to avoid them.**
  A guide to how to ensure you and your patients are safe. Not to be missed
- **Scan4Safety and Medical Device Procurement. Latest update from a Demonstrator Trust**
  The latest updates and when can we see savings?
- **Issues with Bariatric beds and Bed Sides**
  A guide to how to ensure you and your patients are safe.
- **Gas or Air Doctor?**
- **Dose Error Reductions - Does it save lives? Why is it not mandated?**

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# VISITORS TO THE PERIOPERATIVE ENVIRONMENT RECOMMENDATIONS FROM AFPP

People are the main source of micro-organisms that increase the risk of surgical site infection (SSI) for patients undergoing surgery, therefore the number of visitors to the theatre environment should be restricted. Although surgery takes place in numerous types of settings, a patient's surgical outcome is greatly influenced by establishing and maintaining an aseptic environment. The aim of all perioperative personnel must therefore be to minimise the introduction of micro-organisms into the perioperative setting.

From both an infection prevention and the patient's right to privacy, all departments must have written procedures stating the correct preparation for staff and visitors entering and leaving all areas of the perioperative environment. Staff must be aware of these policies and procedures (DH 2010).

AfPP's Standards and Recommendations for Safe Perioperative Practice 2016 state that a patient's right to privacy and dignity should be supported at all times and that consent should be obtained from the patient for the presence of any visitor/external contractor during the patient's surgical care pathway. All theatres should have a policy in place for the management of visitors/external contractors to the perioperative setting which would cover:

- **External contractors**
- **Medical device company representatives**
- **Work experience personnel**
- **Students**
- **Staff from other departments**

The policy should state the correct protocol and risk assessment processes for visitors wishing to enter the perioperative environment and a control mechanism should be in place to authorise and monitor them.

All persons visiting the operating theatre should be made aware of perioperative etiquette and risk management precautions and, if observing clinical procedures, they should be informed of the control boundaries required within the department in terms of the surgical patient and their own function and purpose.

In recent years credentialing has become a way of monitoring medical representatives who enter the theatre environment, ensuring that they have the correct training to meet the required criteria to enter the environment safely and identify that they have had the necessary vaccinations to ensure patient safety. A recognised Theatre Access Course can support this requirement and provide the necessary qualification for them to be included onto a credentialing programme.

The presence of excessive numbers of people in the operating theatre during a surgical procedure may have implications in terms of infection control, patient privacy, confidentiality and dignity, plus the ability for clinicians to concentrate on the task at hand. Controlling access to sensitive areas such as operating theatres would contribute to the department's efforts to combat healthcare associated infection and support safer patient outcomes.

The Association for Perioperative Practice
Daisy Ayris House, 42 Freemans Way,
Harrogate HG3 1DH
**01423 881300**
**www.afpp.org.uk**
**communications@afpp.org.uk**

Further Information

AfPP Standards and Recommendations for Safe Perioperative Practice
**https://www.afpp.org.uk/books-journals/afpppublications**

AfPP Theatre Access Course – for medical device representatives
**https://www.afpp.org.uk/events/AfPPacademy**

AfPP Visitors and External Contractors to the Perioperative Setting
**https://www.afpp.org.uk/careers/Standards-Guidance**

# Is this a Medical Device?

## Updated guidance from MHRA on whether standalone software or an app is a medical device

**In August last year, we published updated guidance to help you identify the health apps which are medical devices. The guidance specifically focuses on standalone software, including apps - as opposed to apps integrated into a medical device.**

**Valerie Field**
*Interim Group Manager Devices MHRA*

## Why did we do it?

In recent years, there has been a huge proliferation in the number of apps marketed for all sorts of uses. I'm sure your own mobile phones are full of apps that measure the number of steps you take each day, act as calorie counters, or offer dietary advice - all as part of your normal lifestyle. But, there's a fine line between general health or wellness apps and those that prescribe a medicine or diagnose an illness.

Many apps and pieces of stand-alone software currently on the market are classified as medical devices. These include apps which gather data from a person or a diagnostic device, such as heartbeat or blood glucose levels and then analyse and interpret the data to make a diagnosis, prescribe a medicine or recommend a treatment.

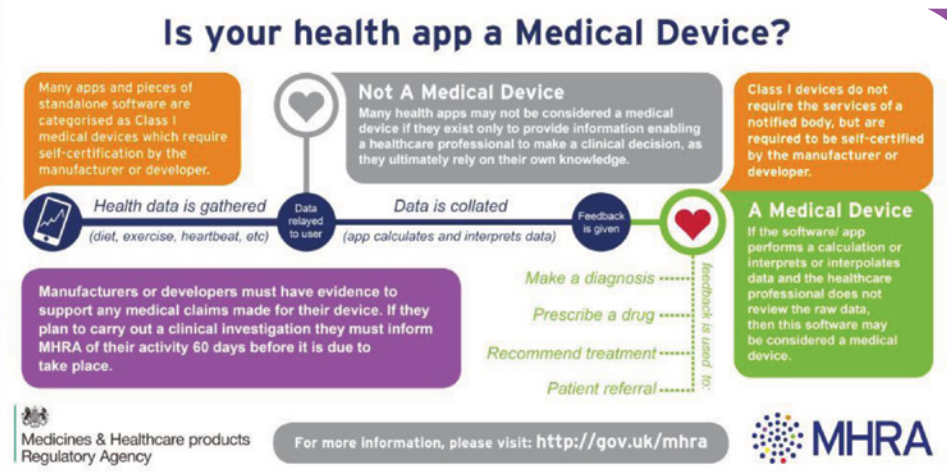
It is important apps which are medical devices comply with medical device regulation and work as expected. Apps that give incorrect diagnoses or prescribe inappropriate treatments may have severe, potentially life-threatening consequences. As patient safety and public health are at the core of what we do, it is important apps are properly regulated.

## Has the guidance been successful?

When we first launched the guidance, we had lots of tweets and re-tweets. More than 90% of the feedback on twitter was positive.

Since then, the registrations for class one apps have more than doubled - although they're still at a low level.

We know the guidance is being viewed - we had more than 4 thousand hits on the website in our first month and currently have around 1500 every month.




## How did we do it?

To help us develop this new guidance, we established a multi skilled cross agency team. Early on, we decided against yet another 20-page document you have to flip from page seven, to page one, and back again!

We wanted something innovative, interactive, and that works for you. Working with key stakeholders, we decided to present the guidance as a step-by-step interactive PDF. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/564745/Software_flow_chart_Ed_1-02.pdf

App users can now use this guidance to check if their health app is a medical device, and what to look for to make sure the app is safe and works. The guidance also helps developers navigate the regulatory system. Developers can use the guide to check what procedures they need to have in place with regard to CE marking and post-market surveillance.

## Next steps and challenges

We're receiving ongoing feedback from users, which helps us improve the guidance. We published a revised version in November 2016 which took on several comments and suggestions from the earlier version.

We'll also need to revise the guidance to take into account ongoing changes to this area as there are new Medical Device Regulations on the horizon. In addition to these, new technologies, complex algorithms and artificial intelligence programmes will continue to challenge how software is validated, verified and regulated. Our aim is always to protect patient safety without being burdensome on the developer. A challenging balance.

If you haven't looked at the guidance already, have a play with it! You can also help us by sharing the guidance and spreading the word. And if you have any suggestions, we would happy to hear them.

# BEHIND THE MACHINES

**Hannah Kowszun** *Director of Marketing and Communications*

Science Council

**It was the morning before the London Marathon and the streets were strangely quiet. I was on my way to a Science Council media training session, where I had invited a selection of brave souls to spend a Saturday honing their interview skills.**

Among them were Paul Lee RSci and Ruth Picknett-Powell RSciTech, medical technicians and enthusiastic advocates for their profession.

Ruth is a Dosimetrist; I had never met a Dosimetrist before and I'm pretty sure I haven't met one since. According to Ruth this isn't unusual, since Dosimetrists, like many other technical roles in healthcare, often remain behind the scenes.

*"We don't tend to be seen,"* explained Ruth. *"We're the hidden section: radiotherapy physics is the bit in between when they've come for their scan and then they go off and they'll come back three weeks later for their treatment.*

*"So [patients] don't tend to see us. We take the CT scans and run them through treatment planning systems. But we also put them onto the machines and check that the information coming out of them is exactly what we've planned, and we give this to the radiographers, who then treat them with it.*

*"You could compare us perhaps to a pharmacist. We haven't said that you should have these pills, but we've made sure the pills you're having are correct and we've then given them to you to take."*

As a lay person with little working knowledge of how the NHS works, I find this fascinating.

So much is made of the oversight and accountability of doctors, nurses, midwives and other frontline personnel in hospitals and other medical facilities, but as a patient you never hear about the people that work out of sight: managing and maintaining the machines that are such a key part of modern medicine.

Paul Lee, Chair of NAMDET and now on secondment with NHS Improvement, would like to raise the profile of people in these kind of roles: *"When I started my professional career in 1986 I walked into the intensive care department and saw patients connected to medical equipment, devices, electronics going on everywhere; little did I believe that there was someone behind the scenes looking after that equipment.*

*"We are fighting our corner, raising our profile. We do the same qualifications, we have to go through the same training programmes, we do degrees and Masters degrees, and we believe it's about time that we receive the same recognition as our other colleagues in healthcare."*

**That's where professional registration with the Science Council comes in.**

For anyone applying science in a professional setting, including the technical application of science, registration with the Science Council provides recognition of standards and competence of professional and ethical conduct.

**There are three registers for science professionals:** Registered Science Technician (RSciTech). Registered Scientist (RSci) and Chartered Scientist (CSci). Which one you could apply for depends on how much experience you've gained, the level of autonomy you have and the amount of complexity within your role.

**Our hope at the Science Council is that by encouraging more people to become professionally registered, it will bring out the hidden workforce within healthcare.**

As Paul puts it, *"We need to let people know that every single machine that you're connected to when you go to hospital – whether it's a blood pressure machine, a laser, a cancer treatment drug – that the people behind the scenes servicing the equipment and teaching people how to use it are trained, qualified and skilled."*

Find out more or start your application today at **sciencecouncil.org/professional-technician.**

# Selfie

**Name:** John Byrne

**Age:** Forty ten

**NHS role and where:** I have just resigned as a Head of Medical Physics, from a NHS Trust and now starting work at Arcomedical Infusion Ltd.

**NAMDET role:** NAMDET Director: Secretary, Regulatory Affairs and Quality Assurance

**Family:** I have been married to my wife, Karen for 28 Years. We met the night before I joined the Army, when I had long blonde hair, okay a mullet. The next time I saw her was six weeks later with a shaven head. She was the only person to recognise me. I have a 16 year old daughter called Sarah-Jayne, who makes me very proud every day. She has recently completed her GCSEs and got 7 grade As and 5 A*s.

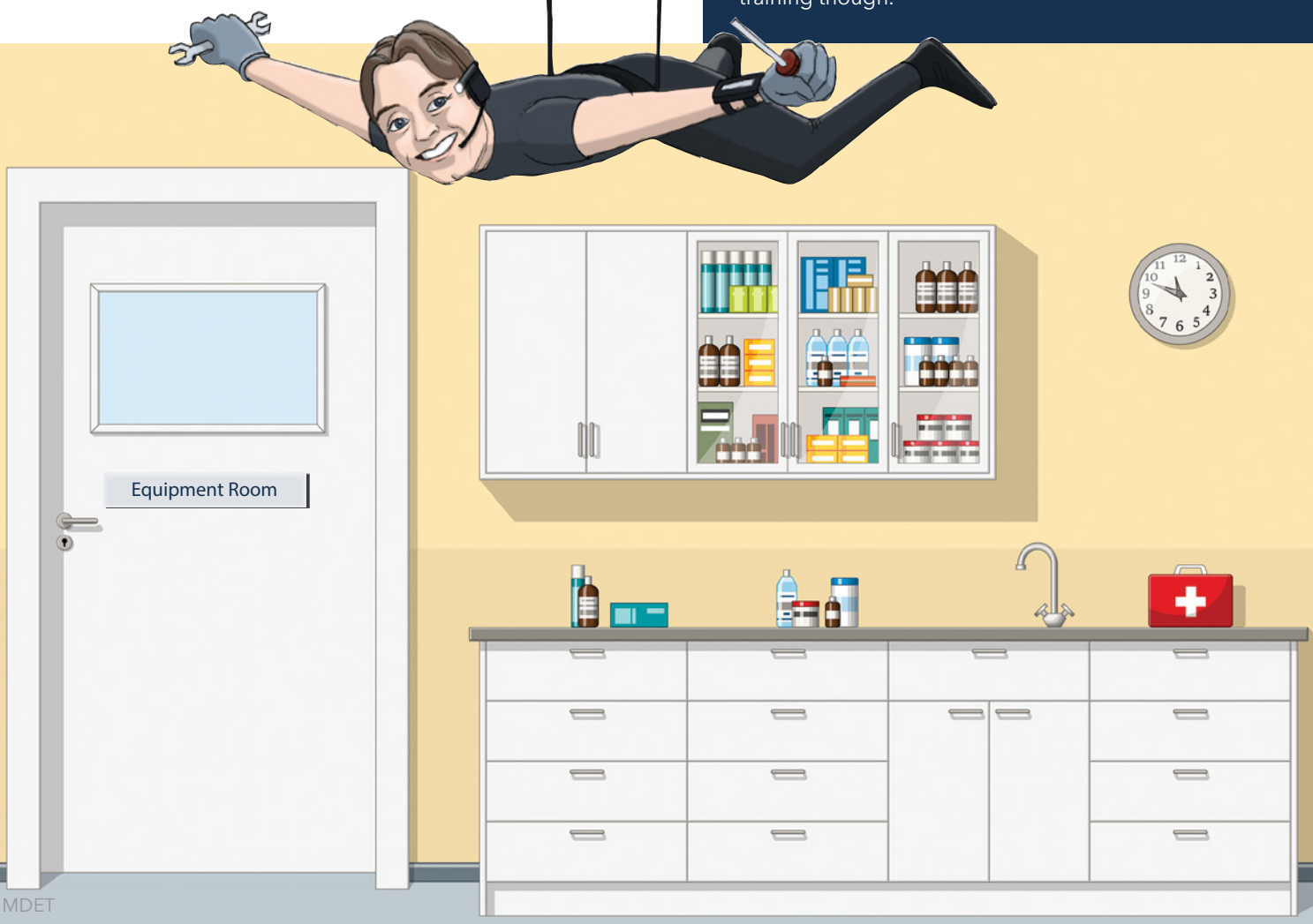
**Hobbies / interests:** I have many hobbies, however they are mainly sports. I am a keen tennis and badminton player, both of which, I play throughout the year. I am also a keen jogger. I enjoy skiing too, when I can

**What do you find most challenging in your NHS role?**
Trying to implement change – when I manage to get it to happen it is great, however this is rare.

**What has been your most significant accomplishment in your NHS work?**
There have been several accomplishments that I have felt proud about.
After six weeks of working in the NHS, a Trust that I was working at had my training forms introduced. These were created and implemented Trust wide. The NHSLA that assessed the Trust described the documentation process as exceptional and the best that she had seen in her career. This spurred me on to improving training at many other Trusts that I was requested to work in.
Increasing the PPMs at a Trust that were at 20% in date to over 90% in eight months, while losing 2 technicians, ready for a CQC inspection. I helped set up the NAMDET London and South East Region and was the first chair of this group.

**What changes would you like to see in the NHS relating to medical devices?**
I would like to see all users take responsibility for the devices that they use and ensure that they are trained on the device.

It would be great to see managers at all levels realising the importance of Medical Devices Training. There is too much self certification or no training at many Trusts, even on high risk devices. I have seen some Trusts that do not have a trainer/coordinator. I think that this is a risk. There are some Trusts that are very good at training though.



**What one piece of advice have you received that you feel has been significant to you and worth sharing with readers?**
Do not try to change everything in one day. – I should listen more.

**If you could give one message to the Chief Executives of all NHS Trusts, what would it be?**
That's easy. Join NAMDET and ask your clinical staff to join too.

**What do you see as the most important challenges for NAMDET going forward?**
Owing to the rate of growth of NAMDET members, and the amount of organisations that NAMDET are working with, we need to ensure that we have a management board that grows in line with the expectations of the work NAMDET are currently completing and for future progression. Mind you if this is our biggest problem, then NAMDET has nothing to worry about. I have met so many like minded professional people that want to do more than they are already doing for NAMDET.

**Why do you feel other members of your speciality should join and get involved in NAMDET?**
There really is no other organisation doing what we are doing. We work side by side with all of the government bodies like the CQC, MHRA, NHS Improvement etc. We have Directors working in these organisations. NAMDET are determining the way medical devices are being used in the NHS and private sector.

Being a member of NAMDET means that there are other like minded people doing the same job to a lesser or greater effect. This means that you can get advice from other NAMDET members via the website forum.

You can also take part in the regional forums. There are many now, throughout the UK and you can go to any or all of them. These are excellent for networking with other trainers or from the variety of presentations on offer.

**Which article in the first issue of MDET did you find most interesting and why?**
Biggest and Best Conference Yet. This highlights how fast NAMDET has grown. For Andy and Tammy being able to organise a conference this size was extraordinary. The quality of the presenters was remarkable. I am looking forward to next year's. Andy expects it to be better. He isn't often wrong.

**If you had not gone into the career you have, what would you have been instead?**
I have completed a variety of careers, prior to joining the Army, I was a toolmaker. However when I joined the Army, I specialised in electronics,
I was also fortunate to qualify in other roles, like an Army Physical Training Instructor, Helicopter Abseil Instructor, Ski Instructor – tour leader training, mountaineering courses, windsurf, powerboat and sailing courses. I think that I would have opted for something sport related - coaching.

**If you were granted three wishes what would they be?**
Invisibility – sounds like so much fun
The ability to teleport like they did on the tomorrow people. If you do not know who the tomorrow people are, you are too young.
Win the Lottery and why not! All six numbers, though, not just three.

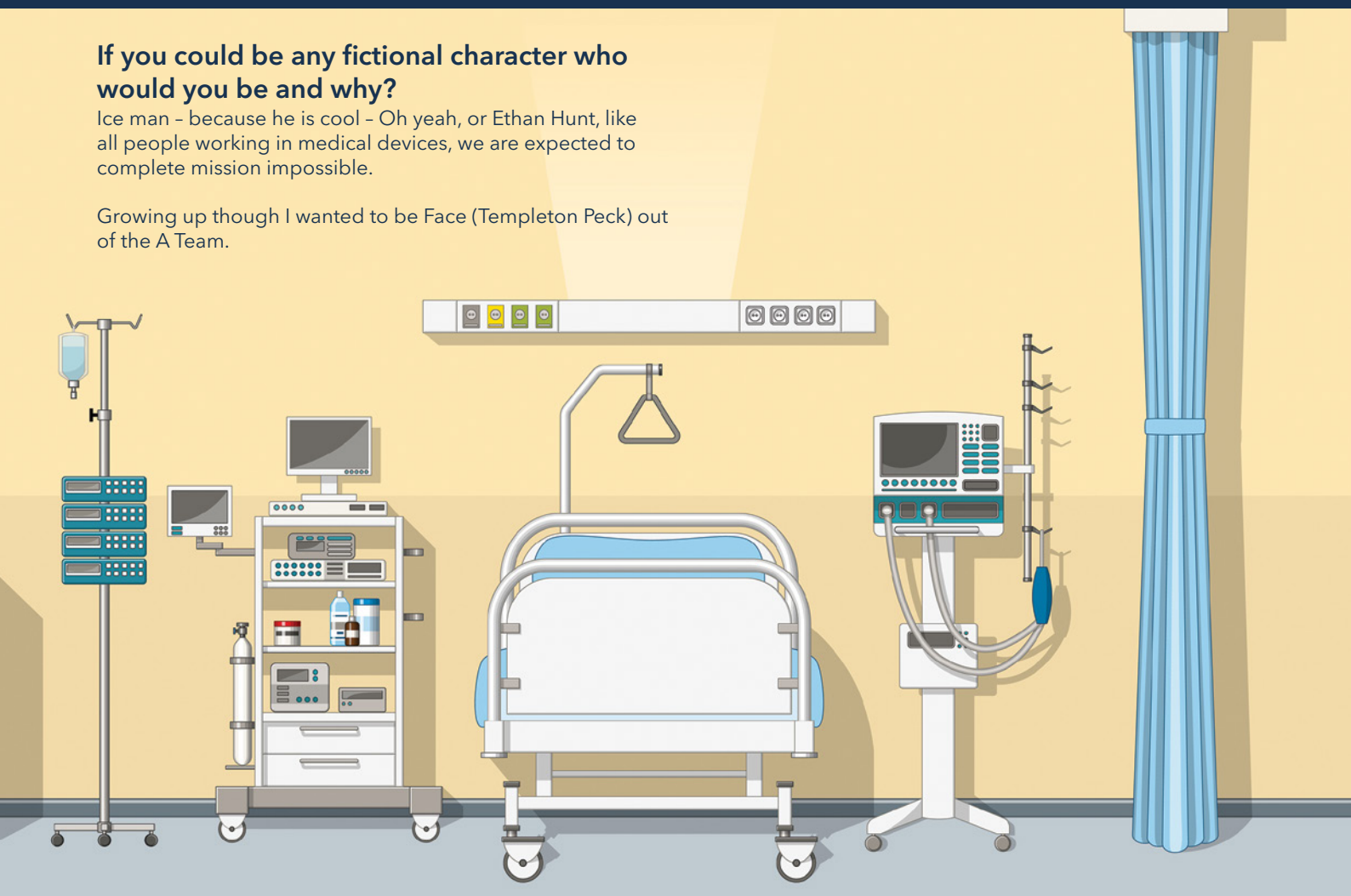
**What's your favourite book or film and why?**
My favourite film is Airplane, it still makes me laugh. "Surely you can't be serious." "Don't call me .." Okay I'll stop.
I have been working my way through the Lee Child books on Jack Reacher, It is a very good read, totally recommended

**What is the person or thing that has inspired you the most and why?**
My Mum. She has worked hard all her life and has helped me out in my business many times.

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

Ice man – because he is cool – Oh yeah, or Ethan Hunt, like all people working in medical devices, we are expected to complete mission impossible.

Growing up though I wanted to be Face (Templeton Peck) out of the A Team.



SHARE
SHEFFIELD HEALTH ACTION RESOURCE FOR ETHIOPIA

6 on-going projects involving more than 65 visits to date and 70+ volunteers

Clinical and Medical Education

Infection Control and Management

Laboratory Medicine Development

Medical Engineering

Dental Health Improvement

Elshadai Children's Village

# SHARING THE BENEFITS OF MEDICAL TECHNOLOGY

**Sheffield Teaching Hospitals are making a big difference to staff and medical equipment at a hospital in northern Ethiopia. Russ Swan talks to some of the people involved in this amazing initiative.**

The pace of development in medical technologies and clinical practice is enough to amaze many people in the UK, but for hard-pressed hospital staff in developing countries the problems are compounded. Not only is the technology racing ahead, but training can lag behind and the pressure on budgets means that even basics can be hard to come by.

For one African hospital though, a British-led programme is making a real difference. SHARE, the Sheffield Health Action resource for Ethiopia, is an initiative which began just after the turn of the 21st century to help spread the benefits of advances in healthcare, medical devices, and hospital management to a new medical centre in Tigray province.

The Ayder Referral Hospital in Mekelle, with about 500 beds, is one of the biggest and most modern in the country. But Ethiopia remains one of the world's poorest nations, with a per capita income of only about $700 per year, and this is of course reflected in the facilities available.

The programme to improve the hospital's facilities began with an idea from Professor Solomon Tesfaye, a distinguished consultant at the Royal Hallamshire Hospital and professor of diabetic medicine at the University of Sheffield. Professor Tesfaye was born in Mekelle, and used his connections in Sheffield and in the Tigray Regional Health Bureau to foster the project. NAMDET board member Andy Flood, whose day job is as medical equipment training coordinator for the Sheffield Teaching Hospitals, explains that SHARE involves both a clinical and a clinical engineering side, providing help and advice to improve healthcare in Ethiopia. Most effort is concentrated in the Mekelle hospital, with some in Addis Ababa, the Ethiopian capital.

Andy is a medical device trainer, but he also has a background of 30 plus years in operating theatres and critical care. He travelled to Mekelle in January 2014, spending three weeks to import and install a cardiac monitor and to train local nurses and technician in its use. He returned for a week in November the same year, as a follow up and to help resolve any issues that had occurred.

The experience highlighted some of the difficulties faced by healthcare professionals in developing countries. *"It's quite a humbling experience to see how they do things out there"* he observes. *"The Ethiopian people I met were all very friendly and open, and very keen to work with us. This has to be the friendliest hospital that I have worked in over my 40 years as a healthcare practitioner."*

*"All of their nurses are trained to graduate level, but few of them have specialist experience beyond the basic qualification. Things that would be*

*easy for us in Sheffield, well, they weren't always so easy out there. They have a new hospital and low-experience staff, but they don't have the supply infrastructure that we do. It can be something of a culture shock."*

A practical way that cultural differences manifest themselves is the tricky task of clearing customs with a consignment of medical equipment and supplies.

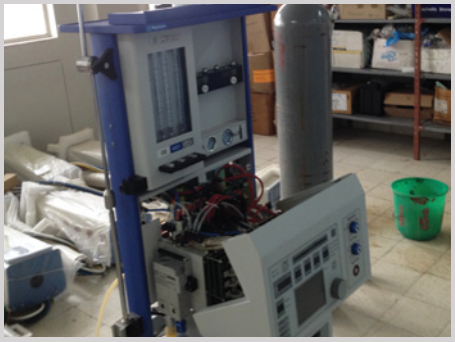
Many countries are understandably sensitive about foreigners entering with quantities of mysterious material, no matter how well-intentioned they may be. Andy recalls that on some trips it has taken several hours, plus letters from professors both in Ethiopia and the UK, and a certain amount of diplomacy, to assure the guards that there was no contraband or munitions in the cargo.

Another, perhaps surprising, revelation was that the most useful people to send out were not necessarily the eager young volunteers that might be first thought of. Newly-qualified doctors, nurses, engineers, and technicians are probably the easiest to recruit from the Sheffield hospitals, but it is the older staff who have experienced a less technology-laden NHS that may have the most to offer.

*"It can be a bit alien to start working again the way we did 20 or 30 years ago, but this is often what really works."*

That's not to say that the Ethiopians aren't catching up, partly at least due to the efforts of SHARE. *"We started off donating some old and obsolete equipment and supplies, but we learned that this isn't always the right approach. There was a danger of using the overseas hospital as a dumping ground."*

Since the programme began, Andy says there has been a noticeable change in the standards of equipment with the increasing ability of the Ethiopians to be able to buy or lease new machinery.



The observation is echoed by Anne Russell, a ward manager, who chaired SHARE from its launch until 2017. *"Over the years we have done lots of different work with them, from clinical support to developing services. I have been every year since 2001 and have now been 18 times. It is almost unrecognisable from when I first went."*

There is still much demand for donations, and the SHARE programme has found a number of practical ways to help the people of Tigray province.

In 2012 they managed to pack a 20ft shipping container with a variety of medical equipment donated by Sheffield Teaching Hospitals NHS Foundation Trust. Along with pre-used ultrasound machines and baby resuscitaires, and vital signs monitors for both children and adults, staff at the Ayder Hospital received numbers of medical and nursing textbooks and other useful supplies.

The wider community in Mekelle also benefit, with this container including educational supplies for an orphanage, sewing machines for a destitute women's shelter, and football kit and memorabilia donated by Sheffield Wednesday Football Club.

Delivering such wide-ranging assistance is an integral part of the SHARE initiative. The group's most recent visit to the country, in early 2017, saw six staff members from Sheffield Teaching Hospitals travelling to St Pauls Hospital in Addis Ababa and Ayder Referral Hospital in Mekelle.

Among them was the new chair of SHARE, consultant virologist Cariad Evans. While the main thrust of activities was to help with infection prevention and patient safety, the improvement of laboratory facilities, and a biomedical engineering project, the group also found other ways to contribute.

*Dental health has become a significant part of the programme, involving everything from supplying donated packs of toothpaste and brushes to training in oral hygiene and even hands-on dental work.*

The group takes a special interest in a children's village to the north of Mekelle, where a large orphanage has benefitted from the generosity of Sheffield children. Hundreds of items of outgrown clothing, including school uniforms for boys and girls, T-shirts, and shorts were collected after an appeal to Sheffield schools, and distributed in Tigray.

*"This means the children can go to their local school with a uniform to wear, and be proud of their appearance, at no cost to the orphanage" says Cariad.*

The team also helped out in the hospital in a very practical way, getting their hands dirty to refurbish and repaint a children's playroom to brighten the atmosphere for its young patients.

The SHARE project is run entirely by volunteers, who use their own holiday time and have no personal funding for their work. Some specific projects attract financial support from within the healthcare sector – the Tropical Health Education Trust THET provided money for an engineering project, and the laboratory programme has had support from a learned society – but otherwise the work relies on the goodwill of Sheffield Teaching Hospitals staff and whatever donations can be raised.


SHARE is beginning to take a more pro-active approach to promoting its work and raising new funds, and to that end has recently launched a new website at **shareshеffield.org.uk**. The group has opened a Facebook page at /ShareSheffield/, and has a fundraising page on goldengiving.com (search for Share Sheffield).

There remains a great deal to be done in Ethiopia, including helping bring procedures up to the levels of current good practice internationally. In a recent presentation about progress at Ayder Referral Hospital, Andy Flood reflected that much had been achieved but there is still work to be done.

He estimated that, if the hospital were to be visited by an outside inspection agency along the lines of the UK's Quality Care Commission (CQC), it would be given a 'pass with concerns'. Some issues would be identified, many of them fairly easy to remedy, which would need to be addressed promptly, but overall the facility would be graded positively.

That's quite an achievement for the healthcare system in Ethiopia, helped in no small way by the generosity of professionals at Sheffield Teaching Hospitals.

# Old world-
## *See One, Do One, Teach One*

# New world-
## *See One, Practice, Do One Competently, Teach Everyone*

**Technology is forcing a rapid change in the role of the clinical teams in hospitals. Although hospital staff are multi-skilled, keeping up to date with product applications and safe use is an ongoing learning process.**

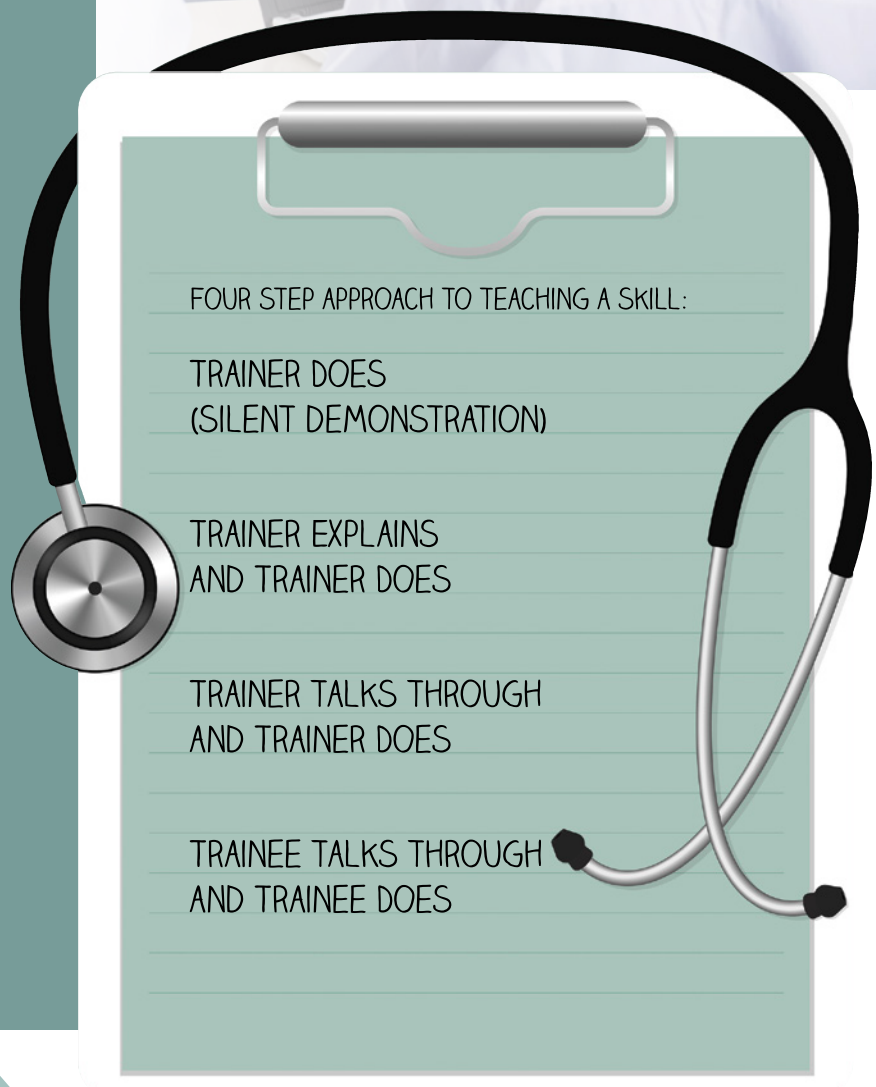
The question is with limited time and resource how do you deliver competence based training that supports quality care and patient safety.

The answer – to use the four steps of teaching a skill ( R Peyton 1998) .

This four-step approach is a quick and effective structure that will promote good safe practice and prevent bad habits.

You can use this method to teach both complex and simple skills. This structure works for teaching senior to senior, senior to junior or junior to junior.

For the trainee, at the end of 4 steps, when they can say it and they can do it, then competence can be evidenced and achieved.




As well as providing competence based training for the trainee/ learner, the 4 steps are also a structure to develop, practice and improve the skills of the trainer……. will share this next time!

***Happy training***

# Selfie

# ROSE PARKER

**Name:** Rose Parker

**Age:** 70 and a half

**NHS role and where:** Medical Devices Coordinator in Liverpool

**NAMDET role:** Board Director, Membership and National Liaison

**Family:** Married for many years and loved it. Single now and loving it. Three children: Ben, Lara and Jake all in their 30's

- Ben works for the Department of Defence in Australia
  - Inna, is married to Ben and is a dietician
  - Josh, is 2 years old, a delight, and my first grandchild
- Jake, is a doctor at Thursday Island Hospital in Australia
  - Alex, is his girlfriend, also a doctor at Thursday Island Hospital
- Lara, did a degree in Japanese, speaks Japanese and lived in Japan for some time. She returned to England recently and has just applied to start a nursing degree

**Hobbies / interests:**
- Gardening – what happened - I used to hate it!
- Cooking and entertaining family and friends
- Travel - I worked in Liverpool and London, Holland, Germany, Gibraltar, Scotland and Australia, before moving back to Liverpool in 2001 and settling down.
- SCUBA Diving – I used to SCUBA dive when living in Australia, but not lately. It is a bit nippy in the UK

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

**What has been your most significant accomplishment in your NHS work?**
- I started in my post of Medical Device Coordinator in 2003 and established a Medical Devices Group, a robust network of medical device trainers and a system for recording training in all areas of practice. This freed up some time to set up the regional group.
- I set up our regional group in the North West in January 2008 with some colleagues. It was the first group to include both NHS and medical device corporate trainers and it quickly became apparent the benefits this collaboration brought to everyone.
- Regional and national meetings take time and I am lucky to be supported in these activities by my managers who also believe this is the best way to discover and build best practice and spread first class training resources, programmes and systems of work

**What changes would you like to see in the NHS relating to medical devices?**
- More networking. Stop 're-inventing the wheel'
- National recognition and sharing of training resources, policies and best practice
- A Medical Devices 'Passport' – NAMDET education programmes will advance this
- The Medical Devices Safety Officer (MDSO) network will also help to standardise and reinforce the work done in the NHS and by NAMDET

**What one piece of advice have you received that you feel has been significant to you and worth sharing with readers?**
People are the most important resource. Inspire and motive people and support them. Network, make friends.

**If you could give one message to the Chief Executives of all NHS Trusts, what would it be?**
- A variation on the same theme… People are their most important resource. Support your staff however and whenever you are able to
- Pass this message on to all your managers
- The long awaited pay rise would be good too!

**What do you see as the most important challenges for NAMDET going forward?**
- Our members are our most important resource. Leaders and recruits are needed to take our work-streams forward. The management structure is currently under review to facilitate this. We need to inspire and motive members to support NAMDET
- We need to inspire and motivate members to support NAMDET
- Keeping up the pace is also a challenge after the great Conference we had in November 2016 and the recent growth in membership

**Why do you feel other members of your speciality should join and get involved in NAMDET?**
- It is fun. Join and benefit
- It is rewarding knowing you are helping to shape the national direction

**Which article in the first issue of MDET did you find most interesting and why?**
It was great to see the conference reports, the reviews of the presentations and so many photos showing our members enjoying themselves. I enjoyed the timeline looking back on the NAMDET journey…. but I think I enjoyed laughing at the 'selfies' of Paul and Andy most - not realising I was next!

**If you could be any fictional character who would you be and why?**
- I asked at work and at home and the responses were interesting. 90% thought I may have been a' hippie chick/rock chick' in the 60's. I was.
- My daughter suggested 'Wonder Woman' and did a bit of research. Surprisingly, this character was based on a real life person, a military nurse in her early life. I worked with the United States Airforce in Germany in the 1970's. I like the fact that she is 'solution driven' which reflects my philosophy - 'where there is a problem look for the solution'.

But I like the 'hippie' chick best. Maybe that is where I got my 'free thinking' from

**If you had not gone into the career you have, what would you have been instead?**
From 32 and 55 I was lucky to spend a lot of time at home with my kids. During this time I started to teach childbirth classes which expanded with my teaching qualification to other subjects. My favourite time was teaching first aid and health related subjects out in the Queensland coalmines and on the tourist boats which operated around the Whitsunday Islands. That wasn't a bad life!

**If you were granted three wishes what would they be?**
- A communication network which sends real hugs and kisses. I miss my Josh and would love a bedtime hug or kiss along with my 'Facetime' bedtime story
- Supersonic travel – so I could pop over for the weekend to my family in Australia
- More time – I would love to go out and buy another Tuesday or a weekend just when I wanted to

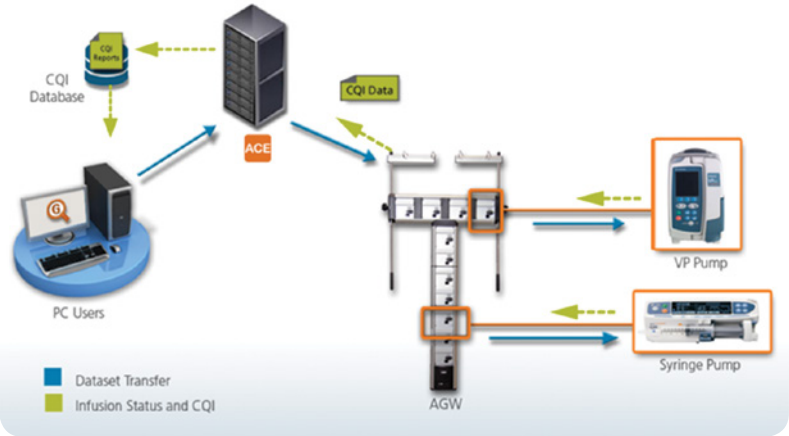
**What's your favourite book or film and why?**
'The Descent of Woman' by Elaine Morgan, which argues the equal role of women in human evolution. I am not a feminist but I love this book. It is fun but it makes you think.

# BD launches Alaris™ Communication Engine

**BD has announced the availability of their Alaris™ Communication Engine (ACE) in the UK.**

The ACE platform provides continuous data transfer and on demand reporting as well as allowing central visualisation of infusions and asset management. The platform helps to improve safety, workflow and cost-efficiency.

IV Medication errors are a serious healthcare issue[1] and those occurring at the administration stage are the hardest to intercept[2]. An Adverse Event due to IV administration may increase the length of hospital stay by 4.8 days[3], and the associated cost can range from £4000- £6000[4-5]




**The ACE platform helps Trusts:**

- Ensure safe and efficient IV medications management
- Standardise infusion protocols
- Minimise the costs related to preventable adverse drug events

To find out more about the Alaris™ Communication Engine visit **bd.com**, speak with your local representative or contact customer services: **0800 9178776**

References: 1. Valentin A, et al., 2009; 2. G.A. Pepper. 1995; 3. Nuckols TK, et al., 2008; 4. Bittner MI, et al., 2013; 5. Martin J, et al., 2008

## Get with the Plan!

The revisions to the European Medical Devices Directives are complete and the changes to the European Medical Device Regulation (MDR) are nearly here and will impact on every company with a CE mark.

Do you have a plan? There may be a three-year transition period for the MDR to allow you to make the changes however, even starting now regulatory departments are going to have an increase to their workload.

**Companies should be planning to -**

- provide more clinical evidence to get new products to market or for high risk products to get CE marked, or even to keep some existing products on the market
- conduct deep portfolio audits to identify and understand the new regulations; one of the key areas is Classification in the majority of cases the re-classification is upwards and this will have a commercial impact with the introduction of Unique Device Identifiers (UDI) - products will have to be relabelled and data made ready to be made publicly available
- conduct a gap analysis, establish a person/team to create an MDR readiness program
- support the existing Regulatory team, analyse resources i.e. headcount, budget provisions etc.

*Regulations are non-negotiable*

And perhaps most importantly, given these changes to the Regulations and also the Quality Management System Standards (ISO 13485), you should have already opened discussions with your Notified Body to understand their plans for designation for the MDR. They cannot apply for designation until 6 months after the MDR's "entry into force" now expected May 2017. Be warned, the process is not quick.

Online courses for Medical Device Regulations are available from HealthCare Skills **www.healthcareskills.com**

## Reducing the risk of oxygen tubing being connected to air flowmeters

NHS Improvement has made available a short new training video to raise awareness around their recent patient safety alert. This alert has been issued to reduce the risk of harm caused from oxygen tubing being connected to air flowmeters. Severe harm or death can occur if medical air is accidentally administered to patients instead of oxygen. The deadline for implementing the actions in the alert is 4th July 2017.

The training video can be found by searching on YouTube for 'NHS Improvement oxygen'. You are encouraged to share the video within your organisation especially with your training colleagues and use during teaching and training session.

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# Alaris™ Communication Engine

## Helps improve safety, workflow and cost-efficiency

IV medication errors are a serious healthcare issue[1] and those occurring at the administration stage are the hardest to intercept.[2]

An adverse event due to IV administration may increase the length of hospital stay by 4.8 days,[3] and the associated cost can range from £4000-£6000.[4-5] There also may be other costs other than financial ones.[6]

In today's healthcare environment your priorities include:

- Ensuring safe and efficient IV medications management
- Standardisation of infusion protocols
- Minimising costs related to preventable adverse drug events

### ACE-Platform is part of the solution

- Providing continuous data transfer and on-demand reporting
- Allowing central visualisation of infusions and asset management


**References**

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