



NAMDET

The Journal of Medical Device Education & Training



NAMDET Conference Highlights

RCN New Infusion Standards

AfPP & MHRA Voices Behaviour Insights





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Welcome to the Official Journal of NAMDET



Welcome to this, the first edition, of our quarterly journal MDET - Medical Device Education & Training. As NAMDET's official journal this will be a major step in allowing us to provide yet another conduit to communicate the many areas of work that we now support.

I joined NAMDET at its inception in 2011 bringing my MHRA knowledge to the management team and became a Director in 2012. As I look back over the years and see how the NAMDET family has grown it makes me very proud. Of course, as in all families, we have had our ups and downs, our successes and tragedies, but it is only by working through the downtimes that makes any family stronger. From a very small group, supported strongly by the Northern area groups of NAMDET North West and NAMDET Yorkshire, we have grown by leaps and bounds. In 2016 we welcomed NAMDET East Midlands and now NAMDET North Eastern regional groups, both of which are very strong and arrive with many ideas to promote and build our organisation.

2016 was a remarkable year for NAMDET which culminated in our best event yet, the Birmingham November conference. This conference was our most attended event ever and proved how our conference organising committee has worked cohesively to pull together an event that is always a balance of hard work and worry. This year's was no different with our venue still with renovations not finished just a few weeks before our conference. But it definitely ended 'alright on the night'. With a delegate attendance of just over 160, excellent speakers and we were extremely pleased to welcome 22 exhibitors. We want to thank them all for their support and input in the past and for all our future projects.



I do not want to say any more specifically about the conference because the event is being fully featured within this issue; except to pick up on the analogy of driving, which was used by various speakers. 'You would not drive a car without wearing a safety belt', 'When you buy a new car you just jump in and drive away, how many people first read the instruction manual?' and 'Cars are easier to drive today despite the increase in technology, can the same be said for medical devices?' These were just a selection of the themes raised. For NAMDET our education



and training platform is also very much driving linked and will be a major focus of our development work in 2017. The Medical Device Driving Licence is already familiar to the more than 5500 professionals who have already completed learning modules. For those who may not be so familiar, let me start by telling you the background to this important learning resource.

The Medical Device Driving Licence was initially conceived by the MHRA some 15 years ago. It includes eLearning education modules on a range of medical device related subjects relevant to those working in the NHS, social care and industry, across multiple disciplines. This was passed over to NAMDET as the appropriate organisation to continue running and building on the excellent foundations put in place by the MHRA. Virtually housed at www.mddl.org.uk it is free to register and open to anybody within the NHS, social care or industry. On completing an online module, and achieving the required pass mark in the assessment, you are awarded a certificate which is stored online and can be sent to your manager or printed for your training portfolio and an entry of completion is made in your Medical Device Driving Licence. This Driving Licence therefore becomes a record of your medical device training.

THE MEDICAL DEVICE DRIVING LICENCE PROVIDES A NAMDET ACCREDITED LEVEL OF BASIC TRAINING THAT IS CONSISTENT, RECORDED AND TRANSFERABLE ACROSS ORGANISATIONS. IT IS DESIGNED TO COMPLEMENT THE IMPORTANT LOCAL EDUCATION AND TRAINING THAT IS DELIVERED BY OUR MANY NAMDET MEMBERS.

In 2017 we plan to update the website and existing learning programmes, including the addition of more modules in the areas that feedback suggests would be of most value. So, if you are reading this journal and would like to either add to your own continuing professional development or are responsible for supporting others in building their knowledge in medical devices, then please register now. It's free, accredited and most importantly, provides valuable knowledge and understanding.

Before I sign off I also need to make a very important thank you to BD/ CareFusion and their Marketing Manager Lynn Wilks for their early and generous commercial support for the MDET Journal. Without this support we would not have been able to proceed with this exciting new initiative. Thank you BD.

So enough from me as I want you to now enjoy this first 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:

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NAMDET: How did we get to here?



THOTH
changed its
name to
TFI

NAMDET members include:

medical engineers, nursing staff, operating department practitioners, medical device trainers, clinical skills trainers, medical device safety officers, risk and governance managers from NHS, voluntary and private sectors.

7th
workshop
NAMDET
was formed

2011
steering
group
established

"For new medical technologies, we will simplify the pathway by which they pass from development into wider use, and develop ways to benchmark and monitor uptake and training needs to enable staff to respond more effectively and flexibly to this dynamic environment..."

(Professor Lord Darzi, Training for Innovation founding chairman.)

Who are NAMDET?

National Association of Medical Device Educators and Trainers (NAMDET) are healthcare professionals who work to promote the care and safety of patients, staff and carers by ensuring that users of medical devices are fully equipped to safely use technology in the fulfilment of their clinical functions. Use errors caused by inadequate medical device usability have become an increasing cause for concern.

The establishment of NAMDET was a response to the requests of professionals working in this speciality. They have identified the need for a nationally recognised organisation operating as a centre of expertise and excellence and providing opportunities and reinforcing the credibility of specialists in this field.

A brief history

- The Department of Health (DoH) were all too aware of the exponential growth of technologies in health, and to this end formed Training Hub for Operative Healthcare (THOTH) with a view to help close the gap between medical device technology and the end-user, whether it is a nurse, healthcare professional, patient or carer.
- **THOTH changed its name to TFI (Training For Innovation).** This was based at Chelsea and Westminster.

The role of the organisation was to:

- Identify gaps in training for newly adopted technology
- Assess training needs for future medical technology
- Recommend new technologies to assist in training delivery
- Maximise benefits of new technology through more effective training and education

- At the 6th TFI conference, there was a discussion group about forming a Medical Devices Training organisation. Training for Innovation members were to develop a framework for the proposed organisation.

- However, such was the need, nationally, for a group that would represent Medical Devices Trainers, that by the 7th Workshop, NAMDET was not only formed, but presenting and introducing the regional groups that had also been formed.

- The aim of this newly formed group was to take up the challenge and maintain the momentum that had already started. A steering group was established in 2011 and was formed from the list of volunteers.

June
2012
first annual
conference

2012
new
management

This was quickly followed in 2012 by a new management group whose focus was to set up the new association and build a business model that would ensure NAMDET was officially registered in the UK.

- TFI were able to fund NAMDET for the first year only. Since TFI handed over the management (in 2011), funding of NAMDET has relied on our corporate membership fees and revenue generated from exhibitors at our annual conference.

- NAMDET had its first national conference in Birmingham on 25th June 2012 and this focused around the work undertaken in collaboration with the National Health Service Litigation Authority (NHSLA) and the Medicines and Healthcare products Regulation Agency (MHRA) on the Top Ten Medical Device Risks for training.

- NAMDET members have access to a comprehensive and informative website and discussion forums and the opportunity to attend NAMDET regional meetings and conferences.

Membership has expanded from other healthcare disciplines that are responsible

for Medical Devices Training, EBME Managers, Clinical Governance, Clinical Technologists/Scientists, Equipment Librarians etc.

NAMDET's mission statement clearly sets out its aims and aspirations and, to ensure transparency surrounding its business transactions and relationships with manufacturers, NAMDET Ltd was formed and registered at Companies House in Cardiff with annual returns and business status recorded for all to see. As in any business set up, an association has a number of directors with a legal responsibility to ensure good governance, financial control and operate in accordance with best business practice.

Current Landscape

- The regions of the UK are often defined by boundaries and geography, and NAMDET hopes to establish regional groups in line with this plan. Board members have been tasked with enabling links and establishing regional group meetings in these clearly defined areas. It is anticipated that initially some of these regions may be harmonised or shared until such time as the membership grows to enable each area to facilitate its own meetings.



The regional Groups are:

- NAMDET Scotland
- NAMDET North-West
- NAMDET Yorkshire, Humber and the North
- NAMDET Midlands
- NAMDET London and the South East
- NAMDET South West
- NAMDET Wales

- *Members do not have to live or work in a regional area in order to attend a meeting. Members and non-members are welcome to attend any NAMDET meeting.*

- Regional meetings are held quarterly. Each region is working on projects for the benefit of NAMDET, nationally.

NAMDET Scotland

- This group has just formed and are scheduling their first regional meeting

NAMDET North-West

- This group is the longest serving group and has been looking at a training database competency framework

NAMDET Yorkshire, Humber and the North

- This group has been looking at training databases and how training information is collated.

- They are looking at the implications and the statement 'what does trained mean?' This follows a defibrillator incident, that went to the coroner's court, in Wales when a member of staff was classed as not being trained, owing to her training having expired the month before.

NAMDET Midlands

- This group is newly formed and will hold the first West Midlands NAMDET Regional Group meeting on 3rd October at Solihull Hospital.

NAMDET London and the South East

- This group has also been looking at training databases.
- They have also been looking at responses to the CQC requirements for Medical Devices training

Other areas of work are:

- Managing 'missing equipment'
- The implications of Wi fi enabled devices and associated connectivity issues.

'BIGGEST AND BEST CONFERENCE YET'

The National Association of Medical Device Educators and Trainers (NAMDET) is growing and taking on new responsibilities, as its sixth national conference confirmed. Russ Swan captures the valuable insights delivered by the highly respected and entertaining speakers.

Opening proceedings at the Birmingham city centre Holiday Inn, NAMDET conference planner Andy Flood described the event as the "biggest and best conference yet, with more delegates and more trade stands than we've ever had in the six years we've been going."



NAMDET chairman Paul Lee opened by highlighting that NAMDET is, of course, heavily involved with the NHS, and is forging links with the US Life Sciences Educators and Trainers Network (LTEN), a long-established American organisation with a similar remit. NAMDET is seeing increasing signs of its acceptance within the sector, and has for example provided a member of an interview panel for an NHS

appointment: "I know who got it, because I can see them here today!"

Paul was the first of a number of speakers throughout the conference, to draw a metaphor between medical device training and motoring. "I had a Ford Mondeo, which I was able to collect and drive with no certificate of competency, no training, just a driving licence. Sometime later I changed it for a Mazda,

and the dealer didn't ask me, 'are you trained to drive a Mazda?' No, I used my previously acquired skills."

"But then I nearly crashed it. I was approaching a barrier and I slightly misjudged the length of the car, but what I didn't know was that this car was equipped with an automatic radar system which sensed an imminent collision and applied the brakes. This made me panic a little. That's the point when I thought that I really should read the manual."

“ The point is that we all understand the value of skills training, but you can't realistically expect everyone to read all the manuals - that would take too long. ”

This conference marks a point in NAMDET's development that will see it play an increasingly important role in training within the healthcare sector. The organisation now has a national strategy, a national plan, and a committee of dedicated professionals.



national association of
medical device educators & trainers

Welcome
To NAMDET 2016
Quality Training-Quality Care
Great Britain's only conference for medical device educators and trainers
Birmingham Conference & Events Centre
November 3rd 2016
#namdet2016



NAMDET 5TH ANNUAL CONFERENCE

“ The conference has given me an excellent insight into current developments for NHS Training & Education ”



“ Thank you for an informative and motivating day ”

Over 160 delegates

BIGGEST AND BEST CONFERENCE YET...

“ This year the agenda was especially relevant. I now go home with lots of food for thought ”

20 Exhibitors

“ The venue this year was brilliant with round tables which enabled me to speak to a number of people & have interesting discussions ”

“ Good insight into medical device training and management ”

...but then there is NAMDET
6th Annual Conference 2017
Thursday 2nd November
Holiday Inn Birmingham
Why not come and make this one
even bigger and better...

The following reports highlight the take home messages from the keynote speakers at the conference. Full slide sets are available to NAMDET members via the NAMDET website www.namdet.org If you are not currently a member, you can join now for free, via the website.

REGULATION AND TRAINING: THE DEVIL WE KNOW

Tom Clutton Brock



Dr Clutton-Brock is reader in anaesthesia and intensive care at the University of Birmingham and Queen Elizabeth Hospital Birmingham (QEHB), and clinical director of the Healthcare Technology Cooperative (HTC) scheme. In July 2016 he was named among the top 100 health technology innovators in the world by Hot Topics, an online forum for leaders in technology.

Dr Tom Clutton-Brock delivered a keynote presentation reflecting on the rapid development of medical devices and casting a wary eye to the future

"I'm not sure we've made enough progress in engaging with senior clinical staff. NICE (the National Institute for Health and Care Excellence) is hated by most doctors, who see it as a barrier to the introduction of new technology."

This was the frank opening assessment from Dr Tom Clutton-Brock, consultant anaesthetist at the Queen Elizabeth Hospital Birmingham (QEHB) and the University of Birmingham, and a medical advisor to the MHRA, as he reflected on some of the changes in healthcare technologies and the obstacles still to be overcome.

The pace of change in the sector was a recurring theme, illustrated by a comparison of photographs taken on a critical care ward. The first, taken 34 years ago in 1982, showed huge machines including a 'cupboard-sized' balloon pump. This contrasted with a similar image from just four years later, in 1986, showing a range of much smaller machines - some of which would be recognisable and perhaps even still in service today. To illustrate this technological advance further, he noted, the hospital specification at Birmingham includes the requirement for no fewer than 35 electrical sockets for each new intensive care bed.

Attitudes to medical device use have also changed a great deal. He recounted how, as a junior doctor, he was told not to use his department's new pulse oximeter - because it was too expensive. "Can you imagine that today?"

"We worked out that we could afford it if we just used one fewer pairs of surgical gloves per day."

The medical device industry has come a long way over those three or four decades, and there are now around 500,000 different classifications of medical devices in Europe. Of the almost 30,000 different medical device companies, just under half (47%) are small and medium-sized (SMEs), with an average of just two employees per company. In North America, the situation is not much different - an average of three employees.

With the growing use of medical devices, there is inevitably a growth in adverse incidents - but with statistics showing a 12.5 percent increase in adverse incident reports in the three-year period from 2008 to 2010, it is clear that some further investigation and continued vigilance is necessary. In the most recent year for which statistics are available, 2014-15, a total of 14,836 incidents were reported. **That equates to more than 40 incidents per day, every day of the year.**

When responsibility for incidents could be traced, the numbers yielded little information of value. Incidents that could be traced to healthcare establishment or user responsibility accounted for around 30 percent of events, while manufacturer responsibility could be identified in another 30 percent - with both of these demonstrating a moderate downward trend. Events with no established link, in contrast, account for around 40 percent of events and show an upward trend over the 2008-2010 period.

Incidents can occur with low-tech devices as easily as with advanced machinery, he reminded the assembly. He recounted an episode involving the use of a 200-bar Kevlar-wrapped oxygen cylinder - the sort of thing that is "unbelievably widely used". While transferring a patient, the cylinder was placed on the bed between the patient's legs, a common practice, but in the light of this incident one that should perhaps be reconsidered. "Suddenly there was a flash, a bang, and a jet of flame. Everything was on fire. Everything."





In this particular case, attending staff had been properly trained in fire response and the resulting burns were only superficial.

“ The lesson is: do your staff know how to turn off medical gas supplies? It was only because someone did that this incident was contained and did not spread to the gas and O₂ pipework. ”



On a larger scale, he noted that as recently as 2012 a new clinic had opened in Belgium with its gas pipework mixed up. Nitrogen and oxygen were each being delivered from the wrong outlets, which was only first noticed when a patient turned blue.

Illustrating a point about increasing complexity in medicine, Dr Clutton-Brock compared the typical surgical instruments of 50 years ago and today - a simple handheld scalpel compared to a Da Vinci surgical robot. Contrast this with the typical cars of the same periods, a Morris 1000 and a BMW 5-series. “What is interesting is that the car is actually easier to drive today, unlike the surgical tools. *We forget that the training burden on people is absolutely enormous.*”



- such as in flight or in theatre - when the majority is just not enough.

Checklists, he told the audience, are good “because you have to do the whole thing, you spot the things you do not expect to be there.”

“This even extends to the surgeon introducing himself when entering theatre.” The challenge he acknowledged was that these ideas are not universally welcomed by surgeons.



Concluding on the vexed issue of device regulation, he had two observations. Regarding the likely departure of the UK from the European Union, he hoped the country would follow the Swiss model and simply agree to continue with European approvals rather than setting up a new system of British Standards.

And on regulation in general? “I have to say that I do think regulation makes things safer. It used to be fun to build a device in the garden shed, but those days are past.”



As an aside, and as another indicator of technological progress, the scalpel illustrated was not a vintage instrument but had been made recently by 3D printing - a technology that could scarcely have been imagined in the 1960s.

Tom Clutton-Brock spoke in support of the use of detailed procedural checklists, rather like those used in aviation, which it seems are the subject of some discussion within the surgical profession. These lists have been developed by pilots and

others to capture the complete sequence of events and checks that should take place at various stages of a flight, in order to ensure that some vital but easily overlooked item is not skipped. Human memory can be relied on to catch the vast majority of items, but there are times

World Health Organization		
SURGICAL SAFETY CHECKLIST (FIRST EDITION)		
Before induction of anaesthesia	Before skin incision	Before patient leaves operating room
SIGN IN <ul style="list-style-type: none"> <input type="checkbox"/> PATIENT HAS CONFIRMED <ul style="list-style-type: none"> • IDENTITY • SITE • PROCEDURE • CONSENT <input type="checkbox"/> SITE MARKED/NOT APPLICABLE <input type="checkbox"/> ANAESTHESIA SAFETY CHECK COMPLETED <input type="checkbox"/> PULSE OXIMETER ON PATIENT AND FUNCTIONING DOES PATIENT HAVE A: <ul style="list-style-type: none"> <input type="checkbox"/> KNOWN ALLERGY? <ul style="list-style-type: none"> NO YES <input type="checkbox"/> DIFFICULT AIRWAY/ASPIRATION RISK? <ul style="list-style-type: none"> NO YES, AND EQUIPMENT/ASSISTANCE AVAILABLE <input type="checkbox"/> RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)? <ul style="list-style-type: none"> NO YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED 	TIME OUT <ul style="list-style-type: none"> <input type="checkbox"/> CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE <input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM <ul style="list-style-type: none"> • PATIENT • SITE • PROCEDURE ANTICIPATED CRITICAL EVENTS <ul style="list-style-type: none"> <input type="checkbox"/> SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS? <input type="checkbox"/> ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS? <input type="checkbox"/> NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS? <ul style="list-style-type: none"> <input type="checkbox"/> HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES? <ul style="list-style-type: none"> YES NOT APPLICABLE <input type="checkbox"/> IS ESSENTIAL IMAGING DISPLAYED? <ul style="list-style-type: none"> YES NOT APPLICABLE 	SIGN OUT <ul style="list-style-type: none"> <input type="checkbox"/> NURSE VERBALLY CONFIRMS WITH THE TEAM: <ul style="list-style-type: none"> • THE NAME OF THE PROCEDURE RECORDED • THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE) • HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME) • WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED <input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

KNOWING WHO'S WHO ON THE WARD AND IN THEATRE

Dr Michelle Dawson



Consultant anaesthetist at Derby Hospitals and clinical advisor to NHS England's Credentialing Oversight Group.

The ability of equipment sales reps to gain access to sensitive healthcare areas would shock the general public if it became known, explained Dr Michelle Dawson, outlining the establishment of the Life Sciences Industries Register

A credentialing initiative, under which medical equipment and pharmaceutical sales representatives will be listed on a central register, and have their credentials confirmed when entering the NHS estate, is in the late stages of development explained Dr Michelle Dawson, a consultant anaesthetist at Derby Hospitals and clinical advisor to NHS England's Credentialing Oversight Group.

The move was first mooted in 2012, in discussions around the replacement of the existing NHS communications network N3 with the new Health and Social Care Network (HSCN). Due for implementation in 2017, HSCN promises to provide a reliable and efficient way for healthcare organisations to access and exchange electronic information.

"It became apparent that there were no checks and balances in place" on people entering and leaving NHS property, including non-public areas, said Dr Dawson.

There are thought to be as many as 30,000 medical industry reps in the UK, with some **estimates of at least 50 reps per day visiting a typical hospital**. "Ask a clinician how many product trials are taking place in the hospital that day, and no one will know. If the public knew this there would be outrage."

Dr Dawson pointed out that reps are not currently required to have any background checks, do not have to have been cleared by the Disclosure and Barring Service (DBS check), and are not listed on any database. There is no formalised system of training in place, and each manufacturer or supplier will provide their own training according to the needs they perceive - this may focus more on sales related issues to close the deal than any standards of behaviour or conduct while in a healthcare environment.

Coming in the wake of recent high-profile cases including Jimmy Savile, it is not acceptable for people to have unqualified access to theatres and wards. "Even if they have an ID card, there is no way to check it. There is no governance behind it, and no credentialing until this register is up and running."

The forthcoming Life Sciences Industries Register is intended to remedy the situation. Current proposals are for a three-level system of qualification and access privileges:

Level 1

No contact with patients or relatives. These people will need a DBS check and be offered flu vaccination.

Level 2

Possible contact with patients or relatives in areas where no invasive procedures are taking place. They will require the DBS check and vaccinations against flu, MMR, diphtheria, tetanus, and polio.

Level 3

Possible contact with patients and relatives in places where invasive procedures are taking place. Requirements as Level 2, plus hepatitis B vaccination for their own safety.

What is credentialing?

Credentialing is a word that may not have been heard much in healthcare circles so far, but is certain to become quite familiar within months. Not to be confused with accreditation, which is the process of winning a qualification or credential, credentialing is the confirmation that somebody does indeed hold the credentials they need in order to gain access to places including wards and operating theatres.

As an illustration of the need for such a register, Dr Dawson recounted the tale of an Operating Department Practitioner (ODP) with a notoriously short temper, who one day in theatre actually threatened to stab a nurse with a pair of scissors. Naturally, this individual was disciplined and dismissed. The nurse in question was, however, shocked to find that same individual back in the same operating theatre six months later, not as an ODP but as a rep for a medical technology company.

Moving from acknowledging the need for a register, and defining its scope, to actually creating and implementing it will be a significant challenge.

"So far, we have cooperation of people that matter - the medtech industry, NHS, and Department of Health." The register will be accredited by the Professional Standards Authority, an independent body which also accredits dozens of other healthcare-related professional registers. Pilot implementation of the Life Sciences Industries Register is set for the first



quarter of 2017, although hurdles remain [and since the meeting we have learned that a proposed stakeholders' meeting for December 2016 has been put back until 2017 - Ed].

"In the meantime, the rules around reps meeting with NHS staff have not changed - i.e. no cold calling, no dropping off equipment without prior agreement."

The register will provide a unique ID card for every medtech and pharmaceutical sales rep. It will be searchable, and show a photograph and levels of training for each representative. As the register

develops it is intended that ID cards will be barcoded so that they can be easily scanned to access registration records, but this will not be part of the first stage of implementation because not all hospitals are yet compliant with the GS1 international barcode standard.

Although some hospital staff might see this as an additional burden of bureaucracy, **this register is an important part of the NHS's duty of care to its users and their families**, Dr Dawson reminded the meeting.



Professor Ann Blandford



Professor Blandford is a human factors specialist at UCL and as she stressed, “not a medic of any kind.”

ECLIPSE is funded by the National Institute for Health Research Health Services and Delivery Research programme (project no. 12/209/27). The views and opinions expressed in the presentation were those of the authors and do not necessarily reflect those of the HS&DR programme, NIHR, NHS, or the Department of Health.

WHEN IS AN ERROR NOT AN ERROR?

Preliminary results of a study comparing the intended and actual delivery of medications by infusion devices have highlighted the need for improved training and standardised reporting

Healthcare professionals might expect that the introduction of new and more sophisticated medical devices would lead to a decrease in error rates for drug administration. They might also expect that situations in which patients are given more intensive treatment would also have fewer reported errors. In fact, as Professor Ann Blandford explained, this is not necessarily the case.

Professor Blandford presented the preliminary results of a quantitative observational study into discrepancies and errors in intravenous medication administration, and their implications for training. This study, known as ECLIPSE (Exploring the Current Landscape of Intravenous infusion PracticeS and Errors) looked into the use of infusion devices across 16 hospitals in England, although data from two of these had not yet been processed. It considered five clinical areas: critical care, general medicine, general surgery, paediatrics, and oncology day care, to uncover valuable information about error rates in the use of medical devices.

One of the first things discovered was just how little UK information has previously been available, with much of the published data being from the USA. Differences in collection methods and the

definition of errors mean that American data is not easily compared to that from the UK.

In the USA, intravenous medication application has been identified as a ‘significant’ topic of concern at the Association for the Advancement of Medical Instrumentation (AAMI)/FDA infusion device summit in 2010. The ECLIPSE study is providing information from English hospitals to discover whether similar concerns should be raised here.

The study found that, although error rates are significant, they are not well quantified – meaning that it is difficult to make use of them. Published data show a headline error rate of anywhere between 18 percent and 173 percent of IV doses given – “depending on how you measure it.”

The question of definitions is also relevant, and in particular the difference between an ‘error’ and a mere ‘discrepancy’ – or for that matter a ‘correction’.

Considering 1739 infusions delivered to 1124 patients, Professor Blandford’s study shows an error rate of 11 percent, and a discrepancy rate of 50.8 percent.



Medication administration errors and severity ratings

	N (%)	C	D	E
Rate deviation	70 (4.0)	58	12	-
Unauthorised medication	60 (3.5)	57	3	-
Administration start time discrepancy	13 (0.7)	13	-	-
Incomplete or delayed completion	11 (0.6)	11	-	-
Expired drug	11 (0.6)	11	-	-
Dose discrepancy	8 (0.5)	6	2	-
Wrong drug/fluid/diluent	8 (0.5)	8	-	-
Omitted medications (not administered at time of data collection)	5 (0.3)	2	3	-
Roller clamp positioned incorrectly or inappropriately	1 (0.1)	1	-	-
Concentration discrepancy	1 (0.1)	-	-	1

ECLIPSE

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Example Category D error

likely to have required increased monitoring /intervention to preclude harm

- "A paediatric patient was receiving an infusion of 500ml sodium chloride 0.45% glucose 5% and potassium chloride 0.15%. The infusion was programmed at 4ml/hr but the prescribed rate was 7.5ml/hr. At the time of observation the infusion should have been running at the higher rate for approx. 2 hours. The patient was clinically stable."

ECLIPSE

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That category E error

likely to have caused temporary harm

- "Patient was administered 2g vancomycin diluted in 250ml of sodium chloride 0.9%. The drug should have been diluted in 500ml of sodium chloride 0.9% and been administered over at least 240 minutes. The drug was observed running too fast via gravity feed. The chart had not been signed to confirm the administration had been double checked as required. The patient complained of pain and red lumps up arm."

ECLIPSE

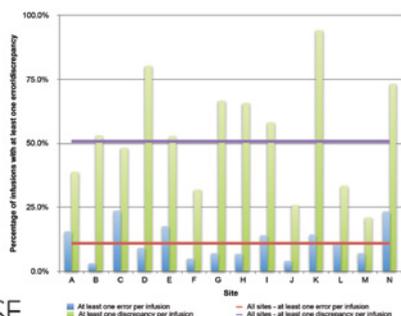
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Discrepancies

Medication administration	
Rate deviation	70 (4.0)
Administration start time discrepancy	36 (2.1)
Incomplete or delayed completion	30 (1.7)
Drug library not used or incorrectly used	39 (2.2)
Other	56 (2.5)
Procedure or documentation	
Tubing not tagged/labelled correctly	376 (21.6)
Documentation of the administration	268 (15.4)
Additive label missing or incorrect	187 (10.8)
Patient identification*	105 (6.0)
Documentation of the medication order	37 (2.1)
Miscellaneous	
	10 (0.6)

ECLIPSE

Variations between sites



ECLIPSE

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Incidents classified as errors include dilution errors and rate of delivery errors, while discrepancies include discrepancies in start times, incomplete or delayed delivery, and a number of procedural and documentation issues. The most common errors were rate deviations and unauthorised medications, and these were often due to poor documentation or verbal instructions.



She noted "huge variability" across the sites, not only in their reported rates but also in their definitions. "Hospitals with tight policies produce a higher discrepancy rate.

Further confusing the matter, it was noted that discrepancies or deviations are sometimes actually 'corrections', such as might be the case when nursing staff identify a prescription error. Different habits and traditions in different hospitals means that treatments such as flushes and KVO (keep vein open) fluids are not always subject to prescription, further complicating the picture.

The introduction of new technology has not yet had an appreciable impact on these issues. Across the study, 29 percent of medication deliveries were via a smart pump and these recorded a 7.5 percent error rate. While that is lower than the 10.8 percent rate for all other infusions (i.e. excluding the ones delivered using smart technology), smart pumps "tend to be used in low error areas anyway, so we think this is not statistically significant." Interestingly, almost 40% of infusions with smart pumps did not have an appropriate drug library entry.

Overall, the ECLIPSE study found that critical care areas, as might be expected, produced fewer errors per infusion than general medicine. It also showed that patient-controlled analgesia (PCA) pumps and syringe pumps gave a lower error rate than gravity fed drips, and that fluids generated more errors than blood products..

Professor Blandford introduced a novel interactive element to her presentation through the use of an online live-polling application. It was perhaps no surprise that for this audience - composed of trainers and educators - the most agreed-with comment was "We should focus on training to minimise errors and discrepancies".

SWISS CHEESE AND SHEEP

Dr Annmarie Brown



Dr Annmarie Brown, Consultant in emergency medicine at Liverpool Hospitals

Even the best technology can be used wrongly, and many healthcare errors are the result of human factors - but the blame and shame approach will not prevent recurrences

The sharp end of the healthcare sector is, without question, the emergency department. Here staff will face a series of unknown and largely unknowable challenges each shift, sometimes working with difficult patients and usually under intense time pressure.

Dr Annmarie Brown, consultant in emergency medicine at Liverpool Hospitals, gave a taste of her world during her presentation on human factors and error reporting. "There is no predictability to admissions, except that it is always rammed. It's a tough environment."

Dr Brown said that around 80 percent of healthcare errors can be attributed to human factors, and that adverse events occur in roughly a tenth of admissions. 400 people are injured or die each year as a result.

One popular visualisation of the way complex systems can fail through human factors is known as the Swiss Cheese Model, originally propounded by James Reason and Dante Orlandella. This views the layers of security in a system as being like slices of Swiss cheese - each one has holes. For a failure to occur, the event has to pass through successive slices without being interrupted - in other words, all the holes have to line up. With enough slices of cheese, this becomes less likely - but still possible.

Underlying factors can be either latent or active. Latent factors include things such as poor equipment or system design, inadequate or missing guidelines, adverse working conditions, lack of resources (understaffing) and poor training and education. Active factors include slips and lapses, mistakes, violations and transgressions. (see diagram opposite)

Nobody in the process is immune from these, as she revealed with a frank recollection of an event in her personal experience. An elderly heart attack patient was brought in, prompting the usual crowd of attendant staff. Dr Brown had been reviewing his test results and had just looked at his blood sugar levels. Turning to the huddle, she issued a series of instructions for his immediate care, ending with "...and give him some insulin please." There was a short silence before a nurse questioned this, prompting Brown to realise the slip of the tongue: "...or adrenalin!"

This simple slip may have been prompted by the fact she had just been reviewing his glucose levels, and the words insulin and adrenalin are not so very different. It was caught immediately, because the flat structure in the department meant that nurses would not hesitate to challenge a questionable instruction. The holes in the Swiss cheese did not line up, and a potential error was averted.

When investigating incidents, the classic NHS approach is widely known as 'blame and punish'. This focuses on identifying a person or group of people who can be held responsible, and taking some sort of action against them.

Incident investigations typically involve four stages -

Initial reporting and raising of concern

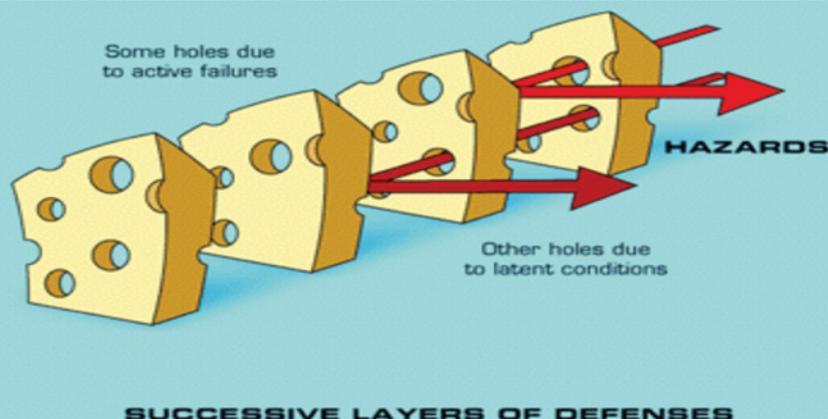
The investigation itself, which considers the universal 'who, what, why, how?' questions

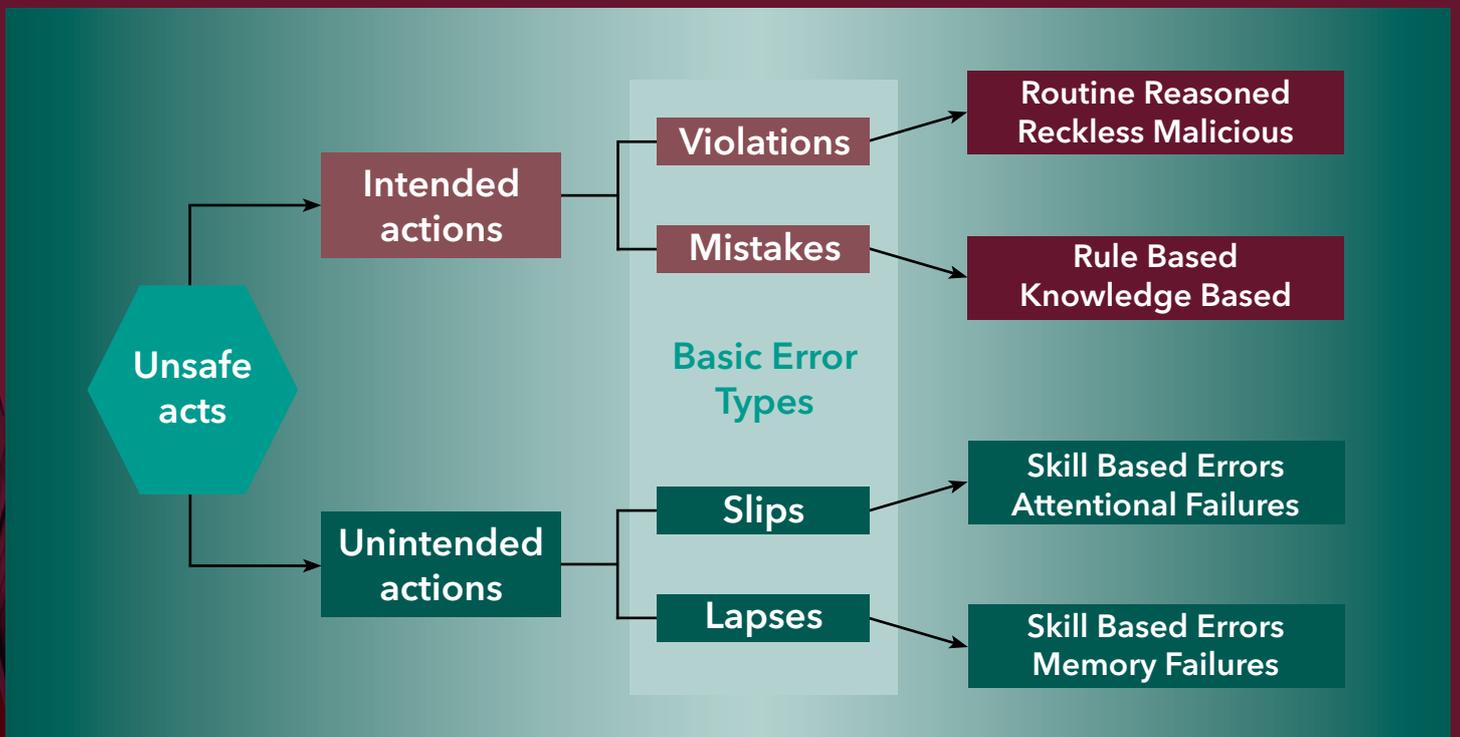
An outcome and action plan, and

Post investigation closing of the loop.



HARM James Reason's Swiss Cheese Model of Accident Causation





A more enlightened and useful way forward, suggested Dr Brown, would be a systems approach which considers the wider context that led to an incident. People do not work in isolation but within a system of rules and procedures, some of which may be formalised and some simply a matter of practice. When an incident takes place, it is a failure of the system rather than the individual that should be addressed.

One model for a systems approach to incident investigation is known as SHEEP: Systems, Human Interaction, Environment, Equipment, and Personal. Each of these elements should be considered as part of the wider quest to pin down what went wrong and why, providing a structured framework to help focus on adopting 'safety-positive' behaviours.

An example of this type of investigation came about in Dr Brown's department when it was realised that important indicators in blood gas analysis could sometimes be overlooked. A patient showed a sharp drop in blood sugars, which was identified on a printout with numbers and a down-arrow graphic. In the high level of activity typical in the department, this indicator was overlooked – but why?

Within the lab results, this measurement was in the middle of a list of perhaps 20 different sets of figures. All measurements can be important, but this mid-table position meant that medics could easily skim over this one. The consequences could be severe, but how can the issue be addressed?

"One suggestion was to provide extra training for doctors at induction to the department, but doctors are already swamped with information at this stage."

“ I hesitate to say this here, in this forum, of trainers, but more training is not always the answer. ”

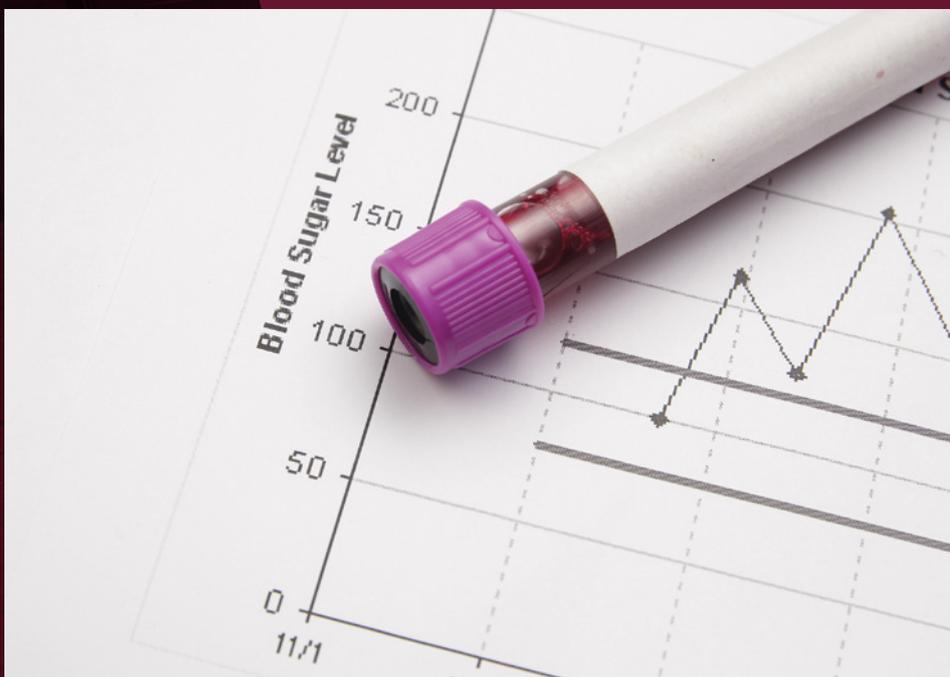
We amended the system, and moved glucose to the top of the sheet."

Did this solve the problem? Yes and no. Dr Brown immediately acknowledged the resulting issue: "We asked – what are we going to miss now? So then we moved potassium to the top of the list. And then haemoglobin..."

We need to make it easy for people to do the right thing and difficult to do the wrong thing.

Like many issues in healthcare and safety, Dr Brown concluded, this is a work in progress. Blame and punish is no way forward, and safety culture should be "learning, informed, and just."

“ To err is human, to cover up is unforgivable, to fail to learn is inexcusable. ”



Mandie Burston



Winner of the RCN Nurse of the Year award in 2015, Royal Stoke University Hospital.

THE PRESSURE IS ON FOR NURSES

At the sharp end of medical delivery, nurses have specific training needs of which device manufacturers and trainers should be aware

If the nature of medical technology has changed in recent years, so has the whole profession of nursing.

Mandie Burston of the Royal Stoke University Hospital, and winner of the RCN Nurse of the Year award in 2015, emphasised that training methods also need to change to reflect the reality on the wards. **"One size does not fit all, and training requires variety to improve standards of compliance and competence."**

One important lesson is to recognise the new pressures under which nurses work, and this is not simply that workloads are high in an often overstretched health service. Training is often conducted in the hospital, which may seem like an obvious choice but may not be the best solution. "It can be a lot to ask of a nurse, to take time out of their day off, fight for a parking spot at the hospital, and for them to hope they might get the time owing."

Motivation is also a key issue: "It's a big assumption that adult professional learners will actively seek training. With today's work schedules and pressures, it is first thing to be dropped or forgotten."

Recent changes to nursing, requiring regular revalidation in order to remain current, can however act in favour of those offering medical device training. Part of the Royal College of Nursing (RCN) requirement for continuing professional development (CPD) is that nurses should have at least 20 hours of participatory learning during the three-year revalidation cycle.

Mandie observed: "Give a nurse a pen, you have her for five minutes. Give her chocolate, you have her for ten.

Give her CPD credit, a certificate, lunch, coffee, biscuits, and free parking, you've got her all day."

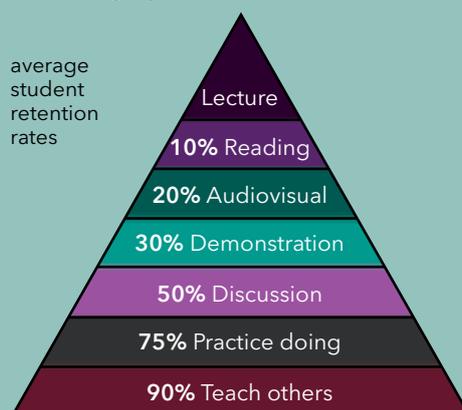
The traditional approach to training in the NHS is "see one, do one, teach one", and this is a good starting point. "Courses need to be full, interactive, and - importantly - include both theory and practical aspects." She introduced the 'learning pyramid' which demonstrates how much more knowledge is retained by interactive practical demonstrations than by mere lectures. She also observed that one undesirable side effect of the move to all-graduate intake is that practical skills are being lost.

"At Royal Stoke I want every nurse to go back to basic. I don't care if they've been nursing for 20 years, they go back to basic."



While the CPD requirements should make a ready audience for new device training, it could also mean that some nurses will turn up purely as a box-ticking exercise. "They have to be reminded that training credits are a minimum, not a maximum."

Learning Pyramid



Source National Training Laboratories, Bethel, Maine

Something that should not be overlooked, she added, was providing good training for trainers. "We educators also need to be educated; this is the only way we can ever improve our performance."

In particular, when a new device is introduced it can "send a shiver down the spine". Techniques she has used include the application of a New Device sticker to the item, to make staff aware of it, and bringing new equipment on to the ward early, on a New Device trolley, to help familiarise staff with it or at least diminish the sense of strangeness.

New Device Trolley



Later, one participant observed that this approach might raise a new challenge - of how to ensure that a shiny new trolley left on a ward was not commandeered for other duties! Mandie Burston summed up by observing that the NHS currently has something like 20 percent of nursing positions vacant, and so pressures on staff seem unlikely to reduce in the near future. Trainers and device manufacturers would do well to keep this in mind. **"What's the thing I worry about most? I don't know what I don't know."**

TREAD SOFTLY IN THE LEGAL MINEFIELD

Questions of liability are not always easily answered when things go wrong when using medical devices

It is probably well understood by professionals in the health care system that patients and members of the public are owed a duty of care, but issues of liability may depend on specific judgements and interpretations of law.

Rachel Brown, a senior associate specialising in clinical negligence at law firm Nabarro, offered a brief legal perspective on when things go wrong. This covered claims for negligence or tort and the Consumer Protection Act (CPA).

Case law in negligence cases traces its roots to the 1932 precedent set in *Donoghue v Stevenson*, in which a woman ordered a bottle of ginger beer at a cafe in Paisley, Scotland. After she had consumed part of the contents, a dead snail was found in the bottle and the customer subsequently fell ill. The manufacturer, a Mr Stevenson, was found to be liable for damages as it was reasonably foreseeable that a failure to ensure a safe product would lead to harm. This case, sometimes called the Paisley Snail case, established the principle of duty of care in English and Scottish law.

The issue of what constitutes a defective product is covered by the Consumer Protection Act (CPA), but that does not mean that interpretation is straightforward. For example, there is a defence known as the state of the art, which can provide some shelter from liability due to limited scientific knowledge at the time but is by no means

a universal get-out clause as an example concerning the National Blood Authority (NBA) and hepatitis C demonstrates.

This blood-borne virus can be spread through transfusions, but even after this possibility became recognised there was no screening test available. This meant, of course, that blood could not be checked before being given to patients. In this situation, Brown challenged the assembly, where the product was known to be potentially flawed but there was no way to confirm this, "was the blood defective?"

In fact, the court found that the blood supplied to patients was defective within the CPA and the European Product Liability Directive. "Some consider this a harsh decision," Rachel Brown noted.

One issue in situations such as this is the matter of reasonable expectation – does the end user have a reasonable expectation that the blood supplied will be 100 percent clean?

In consumer issues, some well-known cases have included whether the coffee in a fast-food restaurant was too hot, and whether dishwasher fluid was adequately packaged. In the case of *Bogle v MacDonalds* in 2002 a scalding injury was sustained by a customer, who claimed the coffee supplied was dangerously

hot. In fact, the court decided that people expected drinks to be hot, that cooler drinks would not be acceptable to customers, and the cup and lid were adequately constructed. The product was not defective.

The case of *Pollard v Tesco Stores* indicates how confusing this area of law can be. A 13-month old child was able to open a bottle of dishwasher powder and consume some contents, despite it being sealed with a 'child-proof' closure. On appeal, the court found that the bottle was not defective, even though the closure did not meet the appropriate British Standard, because the user had only the right to expect that a child-proof top would be more difficult to open but not meet any specific standard of difficulty.

The way in which products are used can also influence the legal view of who is responsible when things go wrong.

It may be a surprise to learn that healthcare professionals can unwittingly find themselves classed as 'producers' of medical devices, not simply users, if they stray beyond standard operating practice in even a small way. In one startling example that Rachel Brown provided, a device had its internal clock set to the wrong time – and this was enough for it to be deemed to be being used outside of

Rachel Brown



Senior associate specialising in clinical negligence at law firm Nabarro.

the manufacturer's recommendations. A simple oversight like this can be enough to make warranties void and transfer responsibility from the manufacturer to the 'producer' – in this case, the medical team using the device.

Rachel Brown concluded with 5 key messages for delegates:

Devices must be used in accordance with manufacturer's recommendations to avoid becoming a 'producer' within the CPA

Consider legitimate 'consumer' expectation, for (vulnerable) patients

Where a device develops a fault, consider whether this requires other devices of the same model/type to be recalled and considered inherently defective (even if they continue to function)

Check devices regularly and report any 'defect' in a device used in a clinical context immediately

Continue to train users of medical devices!

Improve patient safety with Guardrails™: dose-error reduction software (DERS) for infusion pumps

Claire Heron, BD Medication Safety Specialist

Introduction

Delivering intravenous infusion (IV) medication is complex, so it is not surprising that errors are common (Blandford et al., 2016). The problem is compounded by the huge number of IV infusions administered in the NHS every year – approximately fifteen million (NPSA, 2010). Between 2005 and 2010, more than 500,000 medication incidents were reported to the National Reporting and Learning System (NRLS) in England in Wales, with some degree of patient harm occurring in over 86,000 (16%) cases (Cousins et al., 2012). A large proportion of these are likely to be associated with IV infusions, given that errors made during this method of medication administration have been found to be five-times more common than with non-IV medication (McLeod et al., 2013).

Dose-error reduction software can improve patient safety

The development of smart infusion pumps aimed to help reduce human error during the administration of IV infusions (McDowell et al., 2010). The ability for nurses to set a specific infusion rate and volume, and have the infusion administration somewhat automated no doubt has gone some way to achieving fewer errors and increased patient safety. In 2004, dose-error reduction software (DERS) became available on smart pumps to further ensure that medication delivered intravenously is done as intended and within safe limits (Iacovides et al., 2014; Keohane et al., 2005). The key idea is that the DERS software incorporates a drug library, with specified upper and lower limits for drug doses, concentrations and infusion times (Manrique-Rodriguez, 2014). The user is alerted when the smart pump is programmed to infuse a drug outside of the set limits, allowing the parameters to be checked and altered before the infusion begins, so avoiding potentially dangerous administration errors (Manrique-Rodriguez, 2014). Despite DERS being an important advance in patient safety, only a minority of NHS Trusts and Health Boards are using DERS of some type (Iacovides et al., 2014).

Guardrails™

Guardrails™ is a DERS suite from BD Infusion division (formerly CareFusion), developed specifically to address infusion medication errors and provide the tools to audit infusion drug use in order to further refine IV administration and patient safety (Vanderveen, 2010). It is available on all Alaris™ syringe and volumetric infusion pumps.

The drug library in Guardrails™ DERS can be adapted to each clinical area within a hospital, to reflect different drug dosing across different patient groups. Different care areas are referred to as 'Suite profiles' in Guardrails™, and infusion parameters can be defined for up to 30 care areas. Within each profile, up to 100 drugs can be listed and customized, giving a total of 3000 drugs with defined parameters across all care areas.

Importantly, all profiles within an institution can be made available on all pumps, so every pump can be moved throughout the hospital between different care areas, and the appropriate drug library is always available, thus maximizing asset utilization (Upton, 2012). The features of Guardrails™ are summarized in Table 1.



Alaris™ GP Plus Volumetric Pump with Guardrails™



Alaris™ VP Plus Guardrails™ Volumetric Pump



Alaris™ GH Plus Syringe Pump with Guardrails™



Alaris™ CC Plus Syringe Pump with Guardrails™

Figure 1. Guardrails™ is available on all BD Alaris™ syringe and volumetric pumps. Visit the website for more information: <http://www.carefusion.co.uk/our-products/infusion/infusion-devices/alaris-plus-platform-with-guardrails-safety-software>.

Defining drug parameters for safe infusions

The Guardrails™ suite incorporates Guardrails™ Editor, which is user-friendly, intuitive software that allows drug parameters to be set and reviewed in all profiles before implementation. Drug parameters and settings that can be defined include:

- Concentrations, and limits for open concentrations
- Dosing units in mass units (e.g., mcg or mmol) or ml/hr
- Maximum and minimum dose rate limits, including 'hard' and 'soft' limits
- Bolus feature with hands-on and hands-free settings, with dosing parameters and limits
- The ability to set occlusion alarm pressures for each drug if required

When an infusion is set by the user to proceed outside of the 'soft' dose-rate limits, a warning appears on the pump screen. This prompts the user to check the settings before proceeding.

Soft limits can be overridden, but if hard limits are exceeded, the infusion will not proceed until the dose-rate is set within the hard limits. If exceptional circumstances require a drug infusion to be carried out outside the hard limits, the user can exit Guardrails™ to achieve this and infuse in ml per hour (Manrique-Rodriguez, 2014).

dosing limits, concentrations and infusion rates. This leads to high variability in drug use and promotes an environment in which infusion errors are difficult to avoid (Keohane et al., 2005). Using Guardrails™ on your infusion pumps can help reduce infusion errors by providing a system of defined drug limits which act as a virtual safety net, protecting your patients and your staff. By reviewing the CQI data from the

Table 1. Summary of Guardrails™ features

Guardrails™ drug library	Guardrails™ Editor	Guardrails™ CQI analysis tools
<ul style="list-style-type: none"> • 30 care areas • 100 drugs listed in each care area ('suite profile') • Up to 3000 drugs specified • All suite profiles available on all pumps 	<ul style="list-style-type: none"> • Intuitive interface to set and review drug parameters • Parameters include: <ul style="list-style-type: none"> - Concentrations, and limits for open concentrations - Dosing units in mass units (e.g., mcg or mmol) or ml/hr - Maximum and minimum dose rate limits, including 'hard' and 'soft' limits - Bolus feature with dosing parameters and limits - Occlusion alarm pressures if required 	<ul style="list-style-type: none"> • Integral 'event memory' records details of all Guardrails™ events • Recorded events are saved for up to 1 year • Built-in audit tools include: <ul style="list-style-type: none"> - Summary report of infusions started - Number of hard and soft limit alerts activated - Drug usage report

CQI: Continuous Quality Improvement
*BD, Oxford, UK

A multidisciplinary approach is needed

The safe infusion 'soft' and 'hard' limits and other drug parameters are set by in-house doctors and nurses in collaboration with hospital pharmacists, training staff, IT engineers and Alaris™ medication safety specialists (Quinn, 2011). This process needs to be done with great accuracy and knowledge, since decisions need to be made for every drug in every clinical area (profile), taking in to account different patient profiles. The involvement of a multidisciplinary team is essential for the initial set-up and also for the fine tuning of the data sets following audit.

Guardrails™ comes with a built-in Continuous Quality Improvement (CQI) event recorder or CQI Analysis tool. This extremely useful software records details of all Guardrails™ events in an integral 'event memory', including the type of alarm, the time of the alarm, plus all the programmed pump data pre- and post-alarm (Upton, 2012). Recorded events on Guardrails™ are saved for up to 1 year. In addition, the CQI recorder incorporates important audit tools including:

- **Summary report of infusions started, for those within Guardrails™ and also those outside of Guardrails™**
- **Number of hard and soft limit alerts activated**
- **Drug usage report**

Reviewing recorded pump events and analysing data from the powerful audit tools, drug parameters can be revised where appropriate to fit with actual clinical need, thereby helping to standardize infusion drug use. The data download from infusion pumps can be carried out every 6-12 months by a team of clinical nurse trainers and engineers from BD. The infusion/audit data are collated and analysed, and the resulting CQI report is presented back to the hospital team. Many Guardrails™ users have found the CQI report very useful because it enables them to refine clinical infusion practice (Upton, 2012). This review process again needs input from the multidisciplinary team involved in the set-up of the Guardrails™ profiles, so good communication between departments, stakeholders and BD medication safety specialists is essential for successful implementation (Quinn, 2011).

Guardrails™ can help you comply with safety standards

There is no standardization between hospitals on drug

built-in audit tools, you can refine your drug parameters according to practice and thereby achieve safe, standardized, infusion administration and help increase compliance with national safety standards on the rate and volume of infusion administration and the reporting of incidents of fluid mismanagement (NICE, 2013).

Alaris™ Communication Engine (ACE)

The ideal scenario is to have real time upload/download of data so that changes to drug protocols can be made easily and in a timely manner. This will be possible with Alaris™ Communication Engine which will be launched in the UK early in 2017. ACE will also allow the hospital to download, create and analyse its own CQI data at any time. Hence, being able to quickly identify any infusion medication errors and investigate the cause. For more information on ACE contact your local BD (formerly CareFusion) representative.

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Infusion Standards

Helen Dunn

Lead Nurse Infection Prevention Control, Great Ormond Street Hospital.



Helen was seconded to the RCN to work as the professional lead for Infection Prevention. During her secondment she assisted with the update of the 4th edition of the Standards of Infusion therapy.

The Royal College of Nursing (RCN) has recently published the fourth edition of its Standards, one of its most popular publications supporting nurses in clinical practice. The standards are designed to provide guidance to individuals administering or involved in administering infusion therapy for adults. The Standards are a best practice document for individuals and healthcare organisations to refer to for guidance and advice.



Infusion therapy is broad and covers a wide range of therapies including intravenous (IV), sub-cutaneous, intra-osseous and epidural therapies. Therapies

which are administered through these routes include fluids, medications, blood and blood components and parental nutrition.

Infusion therapy is a healthcare intervention that occurs for the majority of patients receiving healthcare. The complexity of patients, development of advanced treatment regimes and pressures on the healthcare delivery service in the United Kingdom (UK) all contribute to the wide range of settings and environments we see infusion therapies delivered. Many patients receive infusion therapies in their own homes or in satellite healthcare facilities in the community otherwise known as outpatient and home delivered parental antimicrobial therapy (OPHAT). Patients often receive more complex treatment regimens meaning that different routes of delivering infusions need to be considered, including more long term central venous lines.

Considering all of the above the Standards for Infusion Therapy provide evidence based best practice guidance for staff working with infusion therapy and should be used in conjunction with local policy and guidelines.

A number of significant changes are present in this edition of the Standards for Infusion Therapy. These include a rapid evidence review to inform the standards and guidance sections, a section on patient safety, patient experiences in infusion therapy and a section on commissioning and developing an OPHAT service.

Other key changes in the document include removing guidance on specialist infusion therapies which are not common place; these include apheresis and specific devices such as the 'Ommaya reservoir'. Another significant change is that the Standards no longer cover paediatric infusion therapies.

The need to undertake a rapid evidence review was considered central to providing the most up to date available evidence to support the Standards. Full information on this process including the methods and key findings can be found on the RCN website <https://www.rcn.org.uk/professional-development/publications/pub-005703> Conducting a rapid evidence review resulted in a change in the way the guidelines were presented to the end user. There are now clear standard and guidance sections for each topic. Each standard includes clear

information on the strength of evidence identified to support the statement - assessed using an agreed methodology adapted from the Infusion Nurses Society standards (INS 2016) This allows the user of the RCN standards to see whether the standard is based on legislative or regulatory guidance e.g. MHRA or whether it is drawn from a guideline consensus, meta-analysis RCT etc. In some cases, the expert panel has had to use a consensus agreement as there may have been little research or published papers around some standard and guidance sections. For the end user of the standards this addition means that the guidance is not only written by an expert panel, but also drawn from the best available evidence. The standards can also be used by healthcare organisations to update and help create their guidelines and policies should they wish.

The patient safety section is new and contains standards and guidance around patient centred care, documentation, labelling of lines, expiry dates and how to report any product defects. It also provides information on patient safety incidents and research, audit and assurance. This section is of key importance to ensure that all individuals who deliver infusion therapies are aware of the standards which should be met. Many infusion therapies are now given by a wide variety of healthcare professionals including radiographers, healthcare

assistants, Operating Department Practitioners (ODP) and others, therefore it is important that all individuals have standards to refer to which are clear and evidence based.

The commissioning and OPHAT section in the guidance reflects the changing environment and services that deliver infusion therapy. It provides information for those services being commissioned and those carrying out commissioning, as well as providing example business cases for healthcare organisations that may be interested in setting up these facilities.

As well as acknowledging the changing environment and types of infusion therapies that are seen in healthcare facilities, now the Standards also provide key information for users around medical devices. Section four of the Standards is all about infusion equipment and provides standards and guidance around disposable medical equipment including administration sets, add on devices and re-usable medical devices including electronic flow devices and blood/fluid warmers. The inclusion of a separate section for equipment highlights its importance when infusion therapies are administered. The section on reusable medical devices highlights that competence and knowledge of the equipment used is required and this is a regulatory requirement by the MHRA, these devices should be procured in an agreed documented procurement

policy. It also provides a number of guidance statements which individuals and organisations should be aware of including planned maintenance of the equipment, cleaning considerations and documentation of infusions using devices. The section provides further reading for individuals referring them on to the MHRA guidance.

Within the blood and fluid warmer section, the evidence for the requirement of CE marked equipment and the use of warmed fluids for elective and emergency surgery is contained within the standard section. The guidance section contains useful information and associated references for individuals who will be administering infusion therapies using this equipment.

In summary, the recently published Standards for Infusion Therapy by the RCN provide all individuals involved in infusion therapy with a clear evidence based set of standards and guidelines. They are a popular, well used resource by nurses and other individuals working within healthcare and have been updated to reflect the changing needs of the healthcare environment. They are freely available from the RCN website under the publications section. They contain a wide range of standards and guidance relating to infusion therapy including infusion equipment, infection control, infusion related complications and many others.

Table 1: Strength of evidence (adapted from INS 2016)

Strength of evidence	Evidence description*
I	Meta-analysis, systematic literature review, guideline based on randomised controlled trials (RCTs), or at least three well-designed RCTs.
II	Two well-designed RCTs, two or more multi-centre, well-designed clinical trials without randomisation, or systematic literature review of varied prospective study designs.
III	One well-designed RCT, several well-designed clinical trials without randomisation, or several studies with quasi-experimental designs focused on the same question. Includes two or more well-designed laboratory studies.
IV	Well-designed quasi-experimental study, case-control study, cohort study, correlational study, time series study, systematic literature review of descriptive and qualitative studies, or narrative literature review, psychometric study. Includes one well-designed laboratory study.
V	Clinical article, clinical/professional book, consensus report, case report, guideline based on consensus, descriptive study, well-designed quality improvement project, theoretical basis, recommendations by accrediting bodies and professional organisations, or manufacturer directions for use for products or services. Includes standard of practice that is generally accepted but does not have a research basis (for example, patient identification). May also be noted as 'Committee consensus', although rarely used. NICE.
Regulatory	Regulatory regulations and other criteria set by agencies with the ability to impose consequences, such as the; GMC; GPhC; HCPC; HPS; NMC; PHE; organisational policies.

*Sufficient sample size is required with preference for power analysis adding to the strength of the evidence

Note: infusion therapy practice processes and standards should be established in local organisational policies, procedures and guidelines (INS, 2016). All HCPs should be aware of and comply with these.

Who regulates Medical Devices?

Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines and medical devices, ensuring they work and are acceptably safe. Our priority is patient safety; we protect and improve public health through effective regulation. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD).

The broad group of products which are classified as devices is continually expanding. Medical devices cover a wide range of products - from sticking plasters to hip replacements, from contact lenses to personal oxygen tanks and implanted pacemakers. These devices and others like them, can be found in your home once they have been CE marked (a symbol that represents that the device complies with European regulations). There is also the growing use of healthcare apps and stand-alone software, meaning the number of devices available on the market is steadily increasing. And it's not just the products that are diversifying; the users of medical devices are too. Patients and members of the public, along with healthcare professionals, are using medical devices for diagnosis and to monitor health. Medical devices designed for hospital use are also increasingly being used by patients in the home through NHS 'hospital at home' type initiatives. As the number and type of medical devices grows, so does the importance of regulation. This begins with verification, and continues throughout the devices lifetime on the market.

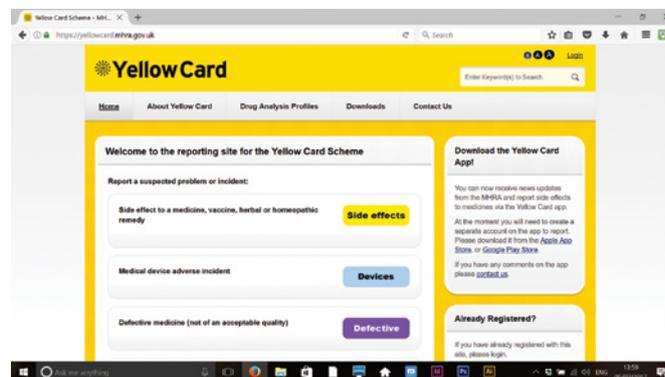
What role do manufacturer's play?

It's important that monitoring of the safety and performance of medical devices continues after verification by a Notified Body. Despite the thorough safeguarding system throughout the EU, problems can still arise when devices are used on a day to day basis.

Manufacturers must continue to actively monitor their safety and performance when they're available on the market. This includes a legal duty to report any adverse incidents involving their devices to the MHRA. An adverse incident could be any event that caused, or almost caused, an injury to a patient or other person, or a wrong or delayed diagnosis and treatment of a patient.

We use these reports to further investigate and review the safety of devices. Additionally, we use this information to require improvements to products, or, if needed, to remove them from market.

Yellow Card Scheme



Anyone can report a problem with a medicine or a medical device via our Yellow Card Scheme.

John Wilkinson
MHRA Director of Devices



Medicines & Healthcare
products
Regulatory Agency

Every report matters and these direct reports are an important source of information. Reports of an adverse incident enable us to develop a robust evidence base of devices safety so we can take action if necessary.

We evaluate any incidents reported through the Yellow Card Scheme together with additional sources of information such as clinical trial data, medical literature or data from international medicines regulators. The purpose of the evaluation is to identify previously unknown safety issues.

Our aim is to ensure that medical devices that people use are acceptably safe. We encourage all those who work with medical devices, as well as people using them, play an important role in helping keep patients safe. Therefore if you have ever used a medical device and had any problems then report to us at: yellowcard.mhra.gov.uk

Editor's note: There is also a MHRA App available. Search App stores for 'Yellow Card'



THE ASSOCIATION FOR PERIOPERATIVE PRACTICE - **STABILITY IN THE CHANGING WORLD OF HEALTHCARE**

The political landscape is continually changing and the government's view of healthcare changes with each new cabinet, with the NHS being used as a tool to gain votes and buy-in from the public. This brings problems for healthcare professionals. In 2012 the NHS was tasked with making in excess of £60bn in savings and this brought a cut in jobs for front line staff. With the loss of mature, experienced members of the theatre team comes the loss of knowledge and expertise. Over the next five years we will see the retirement of more senior/mature members of the theatre teams making the gap in knowledge and expertise even greater. How are we going to fill that gap and how can we ensure that knowledge is transferred to newer members of the team?

AfPP has over 7,200 members and the average age of our membership is 45; with this in mind we are continually reviewing ways of making our Association and theatre work more appealing for the younger generation of healthcare practitioners joining the healthcare workforce; AfPP needs to be providing the right support and education that reflects their needs in an ever changing work environment.

Funding for post registration education continues to dwindle, the loss of bursaries

for student nurses and the increasing tuition fees could well result in fewer student nurses coming into circulation; and budget cuts in all areas may well affect study leave for professionals. These changes are clear threats to the healthcare industry and to patient safety, but they do provide AfPP with the opportunity to deliver a more diverse portfolio of education for our core membership. Whether it be through our regional study days; supported leadership workshops; on line education or whole team training (delivered through our commercial arm), our educational opportunities are readily available for all levels of professionals. As part of our charitable objectives we have a responsibility to facilitate education and practice development that represents good value for money.

Strategic transformational plans within the NHS mean that the number of theatres within the system may change and the regional footprint may be altered to include specialist services and provide different types of theatre practice in many areas across perioperative care. Technology continues to develop apace and this will lead to changes in the way we deliver perioperative care in the future. Whether this be through robotic surgery, accessing information remotely or automated diagnostics, AfPP, working alongside industry partners, needs to be

investing in technology that can support a workforce that requires instant, up to date information.

We are often approached by medical device companies to endorse and/or accredit their educational content in support of their devices. As an organisation we are happy to support this as it not only brings revenue into the Association, but it also ensures that practitioners are working safely and our industry partners are delivering education that is current and meets AfPP's standards and recommendations for safe perioperative practice. We are providing our 'seal of approval' not for their products but for the standard of education that they are delivering to practitioners within their environment.

AfPP's strategy is, and will continue to be, about growing our membership in order to provide a louder voice in the perioperative arena. We will do this through ensuring our membership offering meets the needs of our core audience and that we understand the 'must haves' for our members. Every output from the organisation raises awareness of the Association's good works and encourages potential members to engage with us.

Dawn L Stott
Chief Executive, AfPP



Paul T. Lee | Chairman NAMDET
paul.lee@namdet.org | www.namdet.org

FROM HUMBLE BEGINNINGS...

Back in 2011, when TFI (Training for Innovation) asked if we would consider going on our own, with no ongoing funding and just a small cash injection to get us going, nobody could have thought that there was such an appetite for this newest of professions. Here we are looking forward to 2017, a national conference to be proud of, our own website, you're reading our new official quarterly journal MDET and regional groups are popping up all over the UK. There are national agreed work-streams about to be launched, meetings with Department of Health organisations and invites to sit on groups that advise on regulations, guidance and national strategies.

All those involved in NAMDET are enthusiastic and committed people, with a drive and determination to succeed. We have all helped to establish NAMDET as the voice of medical device trainers and educators across the UK, and we should all be very proud of our achievements to date.

All this in just 5 short years- so what next?

2017 will be a challenge as we have the momentum from conference that we now need to harness, taking on board feedback about how to share resources, training materials, national competencies as well as our work-streams. We need to maintain and grow NAMDET. In 2017,

we are also looking to improve our communication stands and marketing, attend UK patient safety conferences as sponsors, and improve our website. This will all take considerable funding and expertise to take forward. We have a great team already, and many more people out there that we know can help.

At the NAMDET board meeting in Birmingham in November 2016, our 5-year plan was revised with a re-focus on sharing the workload and development of the 'operational group'. We intend to invite experts to join this new dynamic group and they will be given the remit to manage projects going forward and report year-on-year on how we are meeting targets and developing links with industry and colleagues from the UK and further afield.

I encourage our industry partners to contribute where they can and offer themselves up for some of these new roles. After all, NAMDET is unique in embracing industry, NHS and private sector equally, as we all have the same goals and vision.

Our membership continues to grow, doubling since last year, with more regions coming on line. In 2016, the West Midlands group was established and in January a new regional group from North East of England met for the first time and represent many areas of NHS and

Industry. Please continue to encourage your colleagues involved in medical device education and training, or device skills training, to join.

Being actively involved in meetings, professional associations, reading articles and news items all help contribute to ongoing continual professional development (CPD). Therefore, as requested, we will be issuing membership certificates that can be used in annual job appraisals, NMC revalidation evidence as well as your own training portfolios.

For those that haven't yet heard, I have been seconded (until August 2017) to work for NHS Improvement as Patient Safety Lead (Medical Devices) and I'm looking forward to seeing things from a completely different perspective. I hope this will give me greater insight into the statutory national patient safety functions to deliver advice and guidance to the NHS on reducing risks to patient safety, including patient safety alerts.

We still have many doors to knock on, and there are people and organisations who still haven't heard of us. I encourage you all to share the message, get involved and help take NAMDET even further in 2017. NAMDET needs you, so please join if you haven't already, and, as members, get involved. What's stopping you?



status & standing

Raise the status and standing of Medical Device Trainers and Educators



mutual support

Provide a forum for mutual support and assistance between members



represent

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



inform & improve

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



contribute

Positively contribute to reducing adverse medical device incidents

Patient First announces education collaboration with



National Association of Medical Device Educators and Trainers

Taking place at London's ExCeL on Tuesday 21st & Wednesday 22nd November, Patient First welcomes an attendance of over 3,700 healthcare professionals over two days for the latest insight, education, sourcing and networking in and around patient safety and is delighted to be working with NAMDET to run a dedicated conference programme to support Medical Device Safety Officers (MDSOs), Clinical Engineers and members of hospital Medical Equipment Groups.

NAMDET was formed as a response to requests from professionals working in the specialty of medical devices, who identified the need for a nationally recognised organisation, operating as a centre of expertise and excellence, providing opportunities and reinforcing the credibility of specialists in this field.

"We are committed to sharing best practice across the medical device network and we are delighted to partner with Patient First to further our training and support reach to medical engineers, safety officers and trainers, nursing staff and operating department practitioners from NHS, voluntary and private sectors"

says Mike Peel, NAMDET, Director.

The dedicated Medical Device Safety Theatre will be hosted on the show floor giving delegates access to two days of presentations and discussions covering best practice case studies, device safety and procurement topics; from drug error reduction, medical gasses, credentialing, MDDL and education, legality, Infusion pumps, self-regulation and patient representatives.

"Hospitals use an increasingly wide range of medical equipment in order to deliver healthcare

services, in some case tens of thousands", says Event Director Lucy Pitt.

"Medical device risk management and governance is about ensuring that medical equipment is functioning correctly and is safe to use and we are excited to be working together with NAMDET to bring suppliers and MEG's together to embrace an enhanced learning culture around medical devices".

Alongside the Medical Device Safety Theatre, delegates can access hands-on training around infusion pump safety, bladder scanning and ANTT, they can attend Keynote sessions in the Plenary Theatre, listen to case studies from The AHSN Network's Patient Safety Collaboratives in the Best Practice Theatre, learn about technology developments to support clinical care and patient safety in the Safety through Technology Theatre, alongside invaluable networking and learning opportunities.

NAMDET will also be exhibiting on stand J50 alongside over 100 other product and service suppliers on the busy trade show floor.

For speaking, sponsorship and stand packages please contact Lucy Pitt on **02476 719 690** or email l.pitt@closerstillmedia.com

If you would like to attend the event, NHS and qualified safety professionals can put their name on the waiting list www.patientfirstuk.com/waiting-list to be informed when education bursaries are available.

For more information follow on twitter: @patient_first
www.namdet.org and www.patientfirstuk.com



INSIGHTS

Name: Andy Flood

Age: 61

NHS role and where: Medical Equipment Training Coordinator, Sheffield Teaching Hospitals

NAMDET role: Board Director, Conference / Events coordinator

Family: Wife - Alison, William (20) and Edward (17)

Hobbies / interests: Church – Practising Christian, Fishing both Fly and coarse, Football- Sheffield Wednesday (somebody has to)



Selfie



What do you find most challenging in your NHS role?

Getting NHS Trusts to take Medical Device training seriously

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

Leading a national team on developing e- Learning (e4E) medical device programmes in liaison with companies. Being part of the NAMDET Board

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

A more open approach to all aspects of the safe use of medical devices, informing the public in a managed method regarding the amount of money being spent on clinical incidents involving medical devices.

What do you see as the most important challenges for NAMDET going forward?

As we are now growing exponentially, being able to respond as an organisation in a timely manner using the expertise of all our members.

What would you like to see NAMDET do or become in the future?

A well respected professional approachable organisation where we are the first port of call regarding advice on Medical Device issues.

What NAMDET achievement so far are you most proud of and why?

Being able to further promote NAMDET in a professional manner.

What one thing would you like potential new members to know about NAMDET?

That through our membership we will have someone with just the right experience and knowledge to be able to assist in any queries that they may have, and to work ever more closely with our medical company members.

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

My Son (17 yr old) says I most represent Desperate Dan from the Dandy!

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

Probably have been full time in the regular army rather than a reservist. In later years I would have probably gone full time in the Church of England

If you were granted three wishes what would they be?

Sorry don't do wishes.

What's your favourite book or film and why?

I don't read as much now as I used to but my favourite books are quite similar, Hobbit / Lord of The Rings and the trilogy Magician.

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

As a practicing and committed Christian it has to be Jesus Christ.

BEHAVIOUR INSIGHTS

We all share common behavioural traits and, suggests Mike Dixon, Managing Editor of MDET, with a little insight we can start to adapt how we interact with individuals to achieve more positive outcomes.

All of us in our everyday roles need to interact with others, and on occasions those interactions don't go as you had planned or hoped. There can, of course, be many reasons for this, but sometimes do you perhaps feel you both were just not on the same page? This may have been due to the fact that you both had different behavioural personalities. So what are behavioural personalities, and how will understanding more about them help make those interactions more successful next time?

We are all individuals, but centuries of behavioural observation and research tell us that we do share common behavioural traits. And when I say centuries, I actually mean millennia, as right back in 400BC Hippocrates proposed people fitted into four 'humour' types: black, yellow bile, blood and phlegmatic. I am pleased to say that since Hippocrates these have been refined, as suggesting you may have the behavioural characteristics of yellow bile would probably not encourage you to engage with this article much further. However, although they may have been refined, the underlying principles remain the same.

The next name you may recognise is Carl Jung who, in the 1940s, took these ideas forward and developed what is now the basis for many of the behaviour/personality models which you may have heard, or can Google; Insights, DISC, True Colors™, Myers-Briggs Type Indicator (MBTI). What all these variations of the theme confirm is that we can divide our common behavioural traits into categories. Importantly, depending how our behaviour traits synergise with, or challenge, those of whom we are interacting, can affect the success of the outcome. Thankfully, conversely, it also means that even with a very simple understanding of our own behaviours and the behaviours of those we communicate with we hold the potential to help 'get us on the same page' in our communications.

Now this is a short article and can never hope to cover the full detail of even one of these models. If you wish to learn more there is suggested reading at the end. Each specific model has its supporters and detractors, but here we will identify some common themes that can certainly give us enough understanding to help change the way you might approach some interactions and give you the chance to achieve more positive outcomes. As educators or trainers

it can also help you consider how you may structure your activity so it has the ability to engage with different behavioural types in the way that best connects with them.

Some important ground rules to start. You can be successful whatever behavioural type you are, each type has what you may describe as 'strengths' and 'weaknesses'. It is of course not realistic to think we can segregate everybody categorically into a small number of behavioural type boxes. People can display different behaviours at home and work and depending on what they are doing. We need to therefore be thinking more about behaviour dominance in a specific environment such as work. And of course, if we recognise our behaviour dominance we can flex that behaviour and it is this ability that can help achieve a more successful interaction.

The basis of most models start around two axes.

Horizontal, left to right highlights the individual's attitudes from Introvert to Extrovert. Introverts focus inwards towards concepts and ideas whereas Extroverts are more outward focused toward people and objects. The vertical, top to bottom registers the individual's judging factors from Thinker to Feeler. This then gives four quadrants, which represent the four types of behavioural dominance.



We can therefore generalise the traits of these behavioural types and these are shown in the table. Importantly, we can also start to consider how best to interact with each. Perhaps now think about one of those 'not on the same page' moments in the working environment. Firstly, can you identify where your behavioural dominance might be? You have to be honest with yourself.

Where do you think your colleagues would place you? If you are still not sure, perhaps ask them. Now think about the other person(s). Probably by doing this you may start to rationalise some of the challenges and hopefully understand, by thinking about their behavioural type, the best way to approach them in the future.

EXTROVERTED-THINKER

Clues: Fixed eye contact, business-like, every gesture has an endpoint, will make a statement with their dress code e.g power suit, statement jewellery

Can be perceived to be: Strong leaders, very direct and focussed, get things done

Can also be perceived as: Rude, arrogant, over-powering, lacking sensitivity to others, with no feelings influencing them

How to interact with these types: Sit opposite and maintain direct eye contact, speak accurately and with confidence, be direct and get straight to the point, talk about outcomes and results. Highlight clearly 'what's in it for them?'

EXTROVERTED-FEELER

Clues: High energy, excitable, confident, big gestures, people focussed

Can be perceived to be: Imaginative, creative, motivating, engaging, enthusiastic, positive and outgoing

Can also be seen as: Bored easily, lacking focus, not interested in detail, more focussed on the bigger picture

How to interact with these types: Sit opposite and maintain direct eye contact, be informal and show enthusiasm, do some social chit-chat, talk about the enjoyment factor of whatever you have to offer, illustrate your ideas with stories and be able to go off on conversation tangents

INTROVERTED-FEELER

Clues: Minimal eye contact, quiet/soft voice, expect pictures of friends and family on their desks

Can be perceived to be: Caring, people focussed, patient, good listeners, loyal and supportive

Can also be seen as: Too sensitive, very quiet in meetings, withdrawn, indecisive and easily persuaded to do something else

How to interact with these types: Avoid direct eye contact, be personal and personable, ask open-ended questions and draw out any concerns they may have, talk impact on people, provide them time for reflection or to check their decision with others, use words like 'together' and 'we'

INTROVERTED-THINKER

Clues: Very limited eye contact, very slow paced, reflecting speech, minimal gestures

Can be perceived as: Detailed focussed, thorough, the logical person to go to

Can also be seen as: Boring, serious, unapproachable, taking too long to make a decision, critical of others and totally removed from emotion

How to interact with these types: Avoid direct eye contact, keep calm and do not be emotional or assertive, persuade and influence using facts and focus on details, make sure they are 100% correct, give them time to think



That's all well and good in a one-on-one scenario, but as an educator or trainer you often have a group to work with which could well contain individuals of each type. So how can considering behaviours make any difference? The answer is, there is no magic answer. But, by recognising that in terms of their behaviour, and how they will engage with you, they are individuals, you may structure what you do to facilitate the different engagement styles. Try and recognise individual behaviours within the group and adjust how you interact with each individual appropriately. As an experienced educator you will probably already do some of this instinctively. For example, when preparing materials, ensure you have the key message summaries for the 'extroverts', provide the stories and people focus for the 'feelers', give access to the detail and allow the 'introverts' time to absorb and evaluate. It is all about maximising successful engagement with the widest possible audience.

If you have the opportunity to break into groups or pre-determine attendees, perhaps consider doing this by behavioural type and then work with this group in a way that recognises their traits.

Whether one-on-one or a group, to communicate effectively, motivate others and achieve the outcomes you are looking for, it is you that will need to adapt your style to achieve the successful interaction. For example, if you're an Extroverted-Feeler (high energy, top-line, people focussed) then engaging with an Introverted-Thinker (slow paced, detail focused, driven by facts and logic) is going to need the biggest flex in your style. You will need to slow down, dampen the energy, and be detailed and accurate. Get it right and you might be surprised just how different the interaction can be.

Remember, it is not about changing who you are. It is about understanding your behavioural dominance, and those with whom you interact, and flexing your style to achieve the best outcome.

More information

If you're, for example, an Introverted-Thinker then this article will not have been enough detail for you. Here are some other sources of information so you can explore this topic further:

- Briggs Myers, I; Myers, P B (1995) Gifts Differing: Understanding Personality Type. Davies-Black Publishing
- Berens, L V; Nardi, D (2004) Understanding Yourself and Others®: An Introduction to the Personality Type Code. Telos Publications
- Allen J; Brock, S A (2000) Health Care Communication using Personality Type: Patients are Different! Routledge
- Miscisin M (2001) Showing Our True Colors. True Colors, Inc. Publishing

INSIGHTS

Name: Paul Thomas Lee

Age: 51 ½

NHS role and where: Medical Devices Training Manager; ABM (Abertawe bro Morgannwg University Health Board), Morriston Hospital, Swansea

NAMDET role: Director, and Chairman of NAMDET

Family: Married to Andrea (a cardiographer) we met in 1983 and married 11 years later on the Caribbean island of Barbados. We have 2 girls, Jordan aged 20 (just finishing her final year at Cardiff University reading English literature) and Morgan aged 14 who loves art and tattoos!!

Hobbies / interests:

As many as I can fit in, used to have time for golf (got my handicap down to 13) but haven't played for a few years. I enjoy being outdoors, especially sea fishing (in my kayak) with headphones in and at least a mile between me and the shore. Currently revisiting my 1980's mod era and getting out my vintage parka, vinyl records and cassette tapes while browsing the internet to buy myself that 1965 lambretta 125cc scooter I promised myself.

I also love fixing things, I can turn my hand to most repairs, our neighbours are always asking me to fix broken TVs, hairdryers, GHDs and other domestic equipment. It keeps my skills updated I suppose.

Selfie



What do you find most challenging in your NHS role?

Constant change... but I guess that's a stock answer..... trying to keep pace with new technology and innovation, whilst helping nursing colleagues to keep up to date too. Resources must be mentioned somewhere, and trying to do more with less is a constant challenge.

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

Not sure there is only one, I can think of a few that come to mind Helping more than one organisation to standardise on devices and reduce cost, risk and improve patients health and outcomes is probably top of my list.

In 2016 we developed a new learning programme for IV therapy and it took a year to write, develop and fine tune. We think this can be shared across the UK as a ready made training course, even a national qualification.

Raising the profile of the medical device trainer , after all 15 years ago the job role didn't really exist and now we have regional groups in each country of the UK, a national association, a great network of colleagues and friends, annual conferences and well respected in the profession.

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

National minimum safety standards, if devices can't meet these standards they should be removed and replaced. Cars have an NCAP rating, restaurants in Wales have a food safety score (out of 5) so medical devices should have something similar; a national score that covers suitability for clinical use, usability, safety, costs to run, disposal costs too. That would allow us (and manufacturers) to build safer devices and benchmark theirs against competitors devices. This would help



procurement replace the ones that no longer meet the needs, and biomedical engineers to better plan and negotiate when replacing and upgrading the medical device inventory.

What do you see as the most important challenges for NAMDET going forward?

Keeping pace with all that has happened. 2016 was an amazing year and we are now being asked to be involved (and help drive) national initiatives, projects and promotion and we only have a small group of 6 volunteers that run NAMDET Ltd. Four of which are due to (or near) retirement. That leaves a lot of work for a very small group. We need our members, and that includes industry colleagues, to help wherever they can.

What would you like to see NAMDET do or become in the future?

Our vision has always been that NAMDET becomes the 'go to' body for all medical device trainers in the UK. A resource centre, giving assurance, help and advice, investigating errors, incidents, linking in with regulators (MHRA, FDA) NHS Improvement, Scotland, Wales, Northern and Southern Ireland. There is no reason why NAMDET couldn't become an international association too, looking to colleagues from across Europe and beyond.

What NAMDET achievement so far are you most proud of and why?

For me, it's the NAMDET annual conference. Not just the event, but the way in which we have worked together to grow to our current position and standing in just 5 short years.

What one thing would you like potential new members to know about NAMDET?

We have a great network and great contacts that can help. We are here to help, and we need help.. it's a 2 way thing.

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

Inspector Gadget: he has lots of specialist resources and he can fix anything!!

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

I always thought of being a stand up comedian or entertainer.... Not sure my singing voice would get me very far, but I do a very good rendition of Elvis Presley's 'Return to Sender'.

If you were granted three wishes what would they be?

Power of telepathy so I wouldn't have to keep asking people if they understood what I was saying... I would just know... Being able to speak any language... It's such a barrier... Time travel...but I'd go forward not backwards...

What's your favourite book or film and why?

Never been one for books, a bit sad I know but I love reading articles and published work around my specialised subjects. If I was to pick a film it would have to be 'Quadrophenia' it has had the biggest impact on me in terms of who I am, my love of music, early friends (that I have for life) even though I only have a few old photographs from back then to show my children, it still conjures up great memories.

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

I used to work with a friend who was lead resuscitation officer for a health board in Wales (Harry Stevens) and as enthusiastic for learning as me. Many years ago, as an ambulance driver he wasn't able to help save a patient he had been called to assist, as he wasn't trained or allowed and felt helpless. He then set about learning as much as he could, constantly improved his skills, shared what he learnt and eventually helped lead the UK in his profession, culminating in an MBE in 2012.

I learnt that anything could be achieved with hard work, and you should never stop doing what you do well, and never stop trying to make things better. Sadly, Harry passed away in 2016 after a short illness and he will be missed but he has inspired me to keep learning and keep sharing.



Medical Device News

Alaris™ Infusion Central

Alaris Infusion Central is a leading software package that enables you to monitor all infusions being delivered in your wards centrally.

Nurses have many demands on their time, so caring for patients with infusions can be a difficult task. Nurses need to keep track of every infusion and make sure each infusion is delivering the right therapy. Alaris™ Infusion Central (AIC) is the solution. This software package helps staff to check and manage your ward's infusions on your computer or tablet.

AIC gives a detailed summary of infusion status, helping you deliver more efficient patient care by making the best use of your time. Centralizing infusion monitoring may help prevent infection by limiting the number of visits to patients' rooms and bedsides, while giving patients added privacy and reducing predictable alarms. AIC's many benefits include:

- Viewing alerts and alarms centrally, including issues such as occlusions, air-in-line, and near end of infusion
- Easy-to-use, mobile system, saving time and improving efficiency through an intuitive touch-screen interface
- Comprehensive fluid summary which calculates patient fluid balances while displaying inline pressures when used with the Alaris VP and CC infusion pumps



Improve your infusion practice with Alaris™ Infusion Central.

To find out how BD is committed to making infusion solutions simple, seamless and connected visit bd.com

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Cybersecurity in Medical Devices: New FDA guidance



With the media still debating how safe the US election system is from hackers, the FDA are certainly not in doubt that medical device cybersecurity needs to be a high priority. Releasing new

guidance in December, it calls on manufacturers to boost their cybersecurity and incorporate a way to monitor and detect vulnerabilities into the products they make. The FDA also want to ensure manufacturers: understand, assess and detect the degree of risk any vulnerability may present for patient safety; work with cybersecurity researchers and other related stakeholders to share and receive information on potential vulnerabilities; and implement solutions (patches) to cybersecurity issues early, before they can be exploited.

Postmarket Management of Cybersecurity in Medical Devices is available from www.fda.gov - search document number **1400044**

'Miniature' MRI scanner for neonates

A 'washing machine sized' MRI prototype, one of only two in the world, is being tested in Sheffield. The 'miniature' MRI scanner is being used on new born babies to provide more detailed clinical information than a bedside ultrasound scan. The scans can be performed more quickly and reduce the risks and difficulties associated with moving and handling vulnerable new born babies. Professor Paul Griffiths, Professor of Radiology at the University of Sheffield and Honorary Consultant at Sheffield Teaching Hospitals NHS Foundation Trusts, whose team have been working on the design and development for more than 12 years said: "The scanner is much smaller than a standard scanner which enabled us to get it close to the neo-natal unit." He explained, "Babies, particularly with brain problems, are unstable - they can stop breathing or their blood pressure can change in an unpredictable way. If that happens it is useful to have neo-natal staff who are used to that situation in such close proximity, which will improve safety. The MR images themselves provide a more detailed image and can

help provide a more accurate diagnosis. The motivation to keep going with this project is a belief that at the end we will have something that is better for babies with these types of brain problems."



The project is a partnership of Sheffield Teaching Hospitals NHS Foundation Trust, the University of Sheffield, GE Healthcare, and the Wellcome Trust.

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