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MDET

The Journal of Medical Device Education & Training

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GDPR and the NHS

A mock coroner's court

IV medication errors

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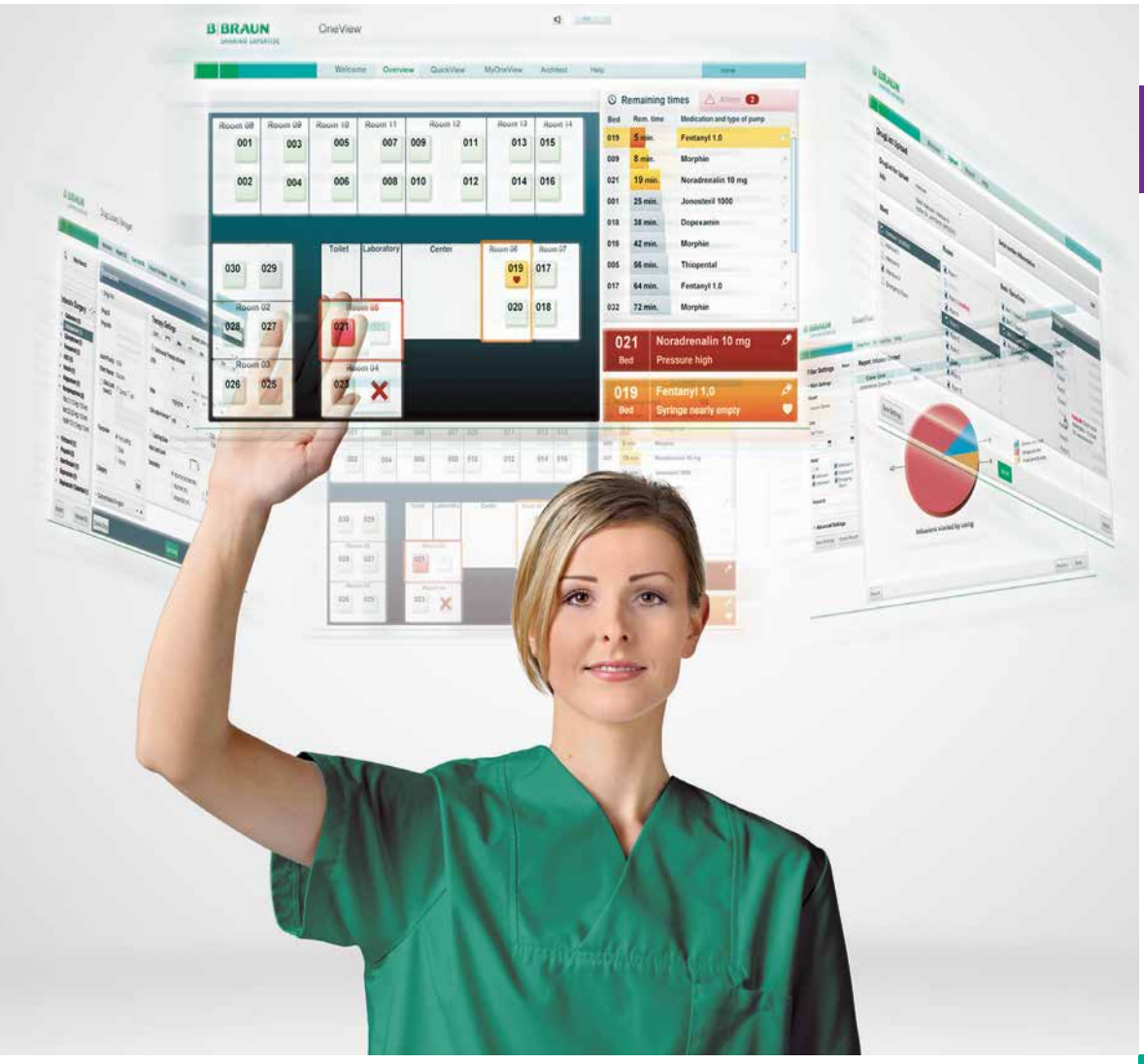

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Paul Lee
NAMDET Editor

Welcome
TO THE LATEST EDITION OF MDET.

We've had a fantastic response to our call out for contributions for the journal so please keep them coming as some of the new articles are included in this edition, and some people submitting for the first time. We have to say a big thank you to our sponsor (BD) and our members across the UK for their stories, articles and updates. We are always interested to hear from our industry colleagues so please share your stories, keep us posted and simply signpost us to subjects of interest that you'd like to hear about and we'll do the chasing.

Hopefully this edition will help raise some new issues and look again at some ongoing themes that seem to be cropping up in the world of medical device training and education. An update on GDPR is included as well as updates from our colleagues at NHS Improvement and working with medical devices in Uganda and how others struggle with what we all take for granted. Richard Olver, Chairman of NAMDET North West shares one of their training courses as a mock coroner's court and the learning outcomes have been a real boon for trainers and device experts in their area.

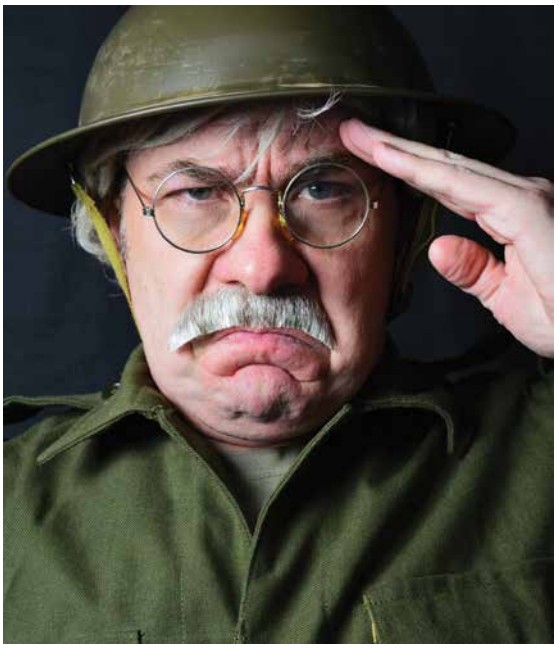
We continue to support our members and work closely on a local and national level and recent regional meetings have been very well attended and a wide range of subjects discussed. A recent invite to join the monthly MHRA's Medical Device Safety Officer (MDSO) network was gladly accepted, where we will be regularly presenting via the monthly WebEx and sharing our activities and projects to those attending the on-line session from across the UK.

Since our last edition some updates that have also been shared via our website include reports from the team at NHSI around incorrect blood glucose reading, MHRA update on assistive technology devices and, of course, the news and media reports around syringe drivers in the 1970s and 1980s and the Gosport inquiry. We were also pleased to share new learning sessions via the e-learning for health website and NAMDET helped lead on these important updates around infusion pumps and safety.

As you open this edition of MDET then our annual conference (5th November) is almost upon us and we are all 'looking forward' to sharing national issues and updating on projects. I can't believe it's been a year already since our last visit to Birmingham, but I know that this year's event promises to be thought provoking, innovative and test our understanding of how we are going to deliver medical device training in the next few decades. I note with interest the emerging market of wearable technology and medical devices, and new apps and software is readily available for a very low cost (and sometimes free) and how our medical device managers, trainers and regulators begin to think about how to control and / or manage these going forward. Using medical devices at home seems to be the way forward too and logging into home networks, IT systems and security are always at the forefront of people's minds. I guess it is going to take a very joined up approach to implement and benefit from these exciting patient safety initiatives and we have to embrace technology as we move into the 21st century, after all when I started working in the NHS a new idea about broadcasting morning TV for the very first time had only just been launched in the UK…… and they said it would never take off…

DON'T PANIC

GDPR has arrived



The passage of the general data protection regulation (GDPR) has generated a lot of headlines about possible fines, a flurry of e-mails, and considerable confusion over what exactly it all means. What do medical device educators and trainers need to be doing to ensure compliance with the provisions of the new laws? Claire Read speaks to data protection officers at two NHS trusts to find out.

When it comes to discussing the general data protection regulation (GDPR), Ewan Robson likes to borrow a phrase from a classic BBC sitcom. The data protection officer at United Lincolnshire Hospitals NHS Trust and Lincolnshire Community Health Services NHS Trust could be mistaken for Corporal Jones when he shares his key message on the new data protection law – namely, don't panic.

Says Mr Robson: *"If you were compliant with the Data Protection Act 1998, then it's likely you're going to be compliant with GDPR 2016 and the Data Protection Act 2018 [by which the provisions of GDPR have been enshrined in UK law]. There are changes, but for frontline healthcare staff there are no real changes."*

It's a line echoed by Andrew Harvey, head of information governance and the data protection officer at Brighton and Sussex University Hospitals NHS Trust and at Western Sussex Hospitals NHS Foundation Trust.

"It's not as massive a change on a day-to-day basis as probably the press and certainly all those e-mails that everybody has been getting are implying," he says.

As that comment identifies, there seems to have been very good reason to be nervous about quite what the new regulation means. Media headlines have centred on the fines that can be levied for breaching it – an eye-watering maximum of £20m or four per cent of annual turnover, whichever is greater.

"If you were compliant with the Data Protection Act 1998, then it's likely you're going to be compliant

And the messages that hit anyone who has ever subscribed to any e-mail list served to suggest specific permission was needed for practically any communication in a post-GDPR world. Hardly reassuring, particularly if you're a medical device trainer who is constantly compiling records of who has and hasn't completed training – and who may well be sending e-mails to anyone who falls into the latter category.

Speak to those for whom ensuring GDPR compliance is an actual job, however, and you're greeted with a calm and much more reserved tone. Mr Harvey – who serves as chair of the National Health and Social Care Strategic Information Governance Network and of the Sussex-Wide Information Governance Group – admits the new regulation does mean *"a massive change behind the scenes".*

"The biggest change to the organisation, and ground level staff don't see this, is the accountability requirement of GDPR," he explains. *"There is so much more paperwork behind the scenes that you have to do to justify how you come to decisions, what you're doing with the information."*

But if you're a medical device trainer, it's more about taking the common sense steps you should have been taking all along: collecting only the information you need, guarding it carefully, and only using it for the purposes for which you originally collected it.

"People are scared," suggests Robson. But in talking through some potential scenarios which may be facing medical device trainers, it becomes clear that his initial Corporal Jones-like assessment is entirely justified.

OK, I'm not panicking… but what if I'm worried?

While the words of Messrs Harvey and Robson are hopefully reassuring, chances are that you may sometimes encounter a situation in which you're concerned about the data protection implications. So what do you do?

Simple: **contact your data protection officer.** This is the person who is responsible for ensuring your organisation is compliant with GDPR and the Data Protection Act 2018, and every NHS body has to have one. He or she will always be the most sensible port of call in the event of any concerns.

If you want to generally read up on the whole area of data protection, meanwhile, then the Information Commissioner's Office website (**ico.org.uk**) contains a wealth of information written in a clear and helpful fashion.

"It's about being open and honest and upfront with people about what you're going to do with their information.

Scenario 1:
An NHS organisation employs a medical device trainer who runs sessions across a number of hospitals. The trainer collects a range of data on delegates: from contact details to details of proficiency, which is in turn shared with clinical directors. What does he or she need to do to ensure GDPR compliance?

Well, first off, stop worrying about whether you can use a previously-collected e-mail address to remind someone their mandatory training is due. The general data protection regulation does emphasise that you must be able to justify processing personally identifiable data. That means that if you interact in any way with any piece of data which reveals a personal identity (or which, when combined with other data you already hold, could reveal someone's identity) you need to be able to explain why it's reasonable to have done so.

But, contrary to what has become popular belief, it's not the case that the only reasonable explanation is that someone consented to your use of that information. The regulation includes six "lawful bases" that can be used to justify processing personal data, and one of them is legitimate interest: the idea that the processing is necessary for your interests, or the interests of a third party.

"As soon as you collect somebody's information for one thing, as long as what you're then contacting them about is related – whatever the distance in time – then there is legitimate interest in doing that," argues Mr Harvey.

"Now, generally, legitimate interest doesn't apply to public sector organisations, but I think that's with their statutory duties. And the undertaking of training isn't a statutory duty of providing healthcare."

So absolutely fine to use that e-mail address you collected on a registration form for an infusion pump training session to inform its owner that he or she needs to complete a refresher session.

When it comes to that registration form, though, it's worth double checking that you genuinely need every piece of information you're collecting. Says Mr Harvey: *"I do question the need for some of the information that's collected on attendance, and I've done it as a trainer myself.*

"Why do we need a signature? All we need is the name of the person who's been there because, when it comes to do it, we probably don't ever do anything with that signature, and do we really need that signature to be scanned and stored somewhere?"

He continues: *"Why do we very often ask for an e-mail address on attendance sheets? Because nine times out of 10 nothing further comes of it."*

It speaks to the idea of data minimisation: ensuring that you're only collecting what you really need; a concept which has always been central to complying with data protection law.

And Mr Robson also emphasises it's worth checking you're explaining why you're collecting the data you're collecting, particularly if it's potentially sensitive. He gives the apparently innocuous example of dietary requirements.

"From a compliance point of view, if trainers are collecting anything that is sensitive, then they need to make people aware of the reason they're collecting it. If they don't tell [attendees] why they're asking for that data, you're in breach of the data protection on fair and lawful use and for a specified purpose."

Comments Mr Harvey: *"It's about being open and honest and upfront with people about what you're going to do with their information. If you tell people you're taking their e-mail address because you might contact them about other courses, then you're OK. It's just being open and honest about how information is going to be used."*

Scenario 2: An NHS organisation engages a trainer from an external body to provide training on medical devices. The individual keeps records of who has attended training; their proficiency; when training next needs to be completed and so on. What measures need to be taken here to ensure GDPR compliance?

For Andrew Harvey, there's not much difference in a GDPR sense between an internal employee and external consultant providing medical device training. *"I think the main thing is that there's a contract of some description in place."*

It doesn't need to be enormously detailed, he stresses. *"Just something that says how you would deal with scenarios particularly around the use or loss of any personal data – which is going to be limited, because as a trainer you'd really only have basic staffing details. But I think it would be good practice to do that."*

It's a view very much shared by Ewan Robson at United Lincolnshire Hospitals and Lincolnshire Community Health Services. *"Medical device training [needs] may be processed by the internal department and then passed on to the training company because there is an ongoing requirement for training. But then you'd have a contract with the organisation to deliver the annual training, so there were no surprises."*

That said, he suggests wherever possible it's best to keep such data in house. *"I would say rather than it coming from the [external] provider [it's better] for it to come from the trust to say you're out of date and this company will be coming in to deliver your training, so you're always controlling your data."*

Scenario 3: With many medical devices requiring the input of personally identifiable data, and with those devices potentially accessible to a range of staff members, how can trainers ensure the devices themselves are compliant with GDPR?

Four words: data protection impact assessment. *"It comes down to what data is being used,"* suggests Andrew Harvey from Brighton and Sussex University Hospitals and Western Sussex Hospitals NHS Foundation Trust. *"If it's a sensitive database on a device, putting the training to one side, you'd want to be doing a data protection impact assessment to make sure it's appropriate."*

Mr Robson agrees, but emphasises such an assessment should be happening a long time before a trainer has a device and a learner in front of them. *"Every medical device an organisation buys, before the trainers get their hands on it, needs to be assessed – as in what type of security is on that device; if it's backed up into the cloud or onto the network."*

An impact assessment, he says, should cover how the device is controlled; who audits its use; and who uses the machine. *"It's all about managing the risk of the data."*

And, he says while trainers shouldn't be responsible for performing these sorts of assessments, they absolutely should get in touch with their organisation's data protection officer if any concerns emerge.

"Trainers are vital, because they become experts in the device and they're always on the end of the phone – I quite often use them – and they may pick up problems as well."

For while GDPR was implemented in 25 May 2018, and its provisions actually absorbed into UK law two days before via the 2018 Data Protection Act, the legal change absolutely does not represent the start and end of the story.

"You can't policy every possible scenario," points out Mr Robson. *"You've got to learn as you go along."* He emphasises that the key thing is to be clear on why you've made a decision to use a specific piece of information in a particular way, and to keep records of that rationale and any advice received from your data protection officer.

"This is what I try to to instil in people – let's pick up the loose ends as we go along. Don't overreact, because in effect we could then affect patient care."

"It's all about managing the risk of the data."

A Mock Coroner's Court

Richard Olver, Medical Devices Training Co-ordinator, The Pennine Acute Hospitals NHS Trust, Chair NAMDET NW shares his insights from attending this enlightening experience.

The set-up

The 'Beast from the East' meant that the March date had to be postponed, so the mock coroner's court event was held at Huddersfield Royal Infirmary (HRI) on the 19th April instead. The organisers were Jayne Blakey and Brian Bottomley from the Medical Device team at Calderdale and Huddersfield NHS Trust; they had supplied us delegates with a 'Who's Who' for the day and other background information, from which we could see that the characters were based on Charles Dickens' Oliver Twist, brought forward from the C19th to the C21st. Role-play learning activity is fraught with issues: some people revel in it and others do not. If planned carefully with this in mind, a mock version of a real event or situation is a way of introducing experiential learning, which is more involving for the average learner than say, a lecture using PowerPoint. The mock coroner's court inquest, presided over by an expert in the field - in this case Barrister Ana Samuels, Counsel and Assistant Coroner for Birmingham & Solihull - is an accurate re-enactment of a real life inquest. This approach provides delegates with a realistic experience of what the coroner's court is like, from opening to verdict.

Attending a mock inquest

An inquest is a legal investigation into a death, conducted by a coroner, where:

- the death is unexpected, such as the sudden death of a baby (cot death);
- the death is violent, unnatural or suspicious, such as a homicide, suicide or drug overdose;
- the cause of death is unknown; or
- the deceased was in a state of detention at the time of their death (e.g. police custody or detained in hospital under the Mental Health Act 1983).

The purpose of an inquest is for the coroner to determine four key facts: who the deceased was, and where, when and how that person came by their death. The main objective for the delegates at the HRI event was to see that all the relevant information was brought forward with clarity. Unlike in a trial where the testimony given by a witness can potentially hurt one party's case, in an inquest there is no such concern as no party is found to be "at fault" at the end of an inquest. The emphasis is on getting to the truth of what happened. The second objective was to come up with practical solutions to prevent a similar death. Following the inquest, and depending on the facts, the coroner may send a report to that person/organisation that has the responsibility to take appropriate steps to reduce the risk of future deaths, under the law; they have a mandatory duty to provide a written response within 56 days.

Many clinical and non-clinical staff including myself have been called to give evidence in an investigation, at court or at an inquest during their career, (coroners' inquests have increased substantially in recent years) - are we prepared? It is important of course that we all understand our responsibility at inquests. The 'Mock' experience provides essential knowledge, equipping delegates with the tools and insight needed to handle inquests confidently and compassionately. The use in this case of familiar fictional names such as Bill Sikes (the deceased) and 'Dr' Bumble, (a medical registrar), gave the event a light hearted feel, (not that the subject is frivolous or to be approached in this manner), we are more receptive and likely to become involved and learn if we are relaxed. It was actually fun to participate as an onlooker, in a non-speaking role of a jury member in a mock inquest, combining the guilty pleasure of sharing 'live' (no pun intended) details of accidental death/manslaughter/murder, but knowing you will not be required to act or speak in role. It seems people through the ages have got a thrill from witnessing court cases from the days of 'Madame Guillotine' through Crown Court to Judges Judy and Rinder. Much like watching a play, but a play where we witness other people's misfortune, with minimal script and valuable life lessons to take away.

Let the inquest commence…

Bill Sikes, the deceased, was a well-known local 'character', a vicious robber, brawler and a regular at the local pubs, as well as the local hospital. He had fallen whilst leaving The Bleeding Heart Tavern at 10pm, hitting his head. When we delegates were given the background on this man, the image in the minds of those who have seen it – and this is the clever part of using fictional characters - was of Oliver Reed from the Carol Reed's 1968 film musical Oliver! Bill obviously was not able to be at his own inquest, but I could see him in my mind's eye, beating Nancy, his girlfriend (in the film and original novel he murders her). To me he was already branded a violent drunk scoundrel - dare I say we all thought 'serves him right'? Toxicology reported a low alcohol level, so at least one of our assumptions was proved wrong by the facts. Subsequently Bill falls again in hospital, and is eventually found dead at 6am. As the inquest progressed and other characters gave their testimony (interrupted at intervals by Nancy's loud accusations and heckling, calmly controlled by Ana), we gained a fuller picture of events. It became clear that a 'he deserves all he gets' attitude to the injured man was wrong and in spite of his shortcomings, he deserved fair and better treatment. Failings included: neurological observations not being taken or recorded, poor history taking (he was epileptic and bruises to his head were noted, but not investigated) and an assumption that his alcohol intake was causing all his symptoms (including his fitting). Dr Sidney Carton actually wrote 'sleep it off' as Bill's management plan – as recorded in his notes. Gradually through questioning and testimony a picture formed of a series of interconnected events rather than a single one - events that led to a man's death, not a good man admittedly, but since when did judgement of them influence the care we should give to others?

So, what was concluded? Bill Sikes, of Jacob's Island, London, died in hospital at around 6am from a head injury. Although the cause was an accident, there was negligence in his treatment that meant that potential life-saving surgery was not carried out: he could have survived. The 'fatal' chain of events, from the failure to scan Bill's head, (in spite of the history of a fall and a bruise noted on the right side of his head), to lack of neurological observations and obtaining a timely medical history, could have been broken at several points by good observation, communication and care.

Concluding proceedings

Ana closed proceedings with two reviews of the case, one from The Trust itself, and an independent review ordered by the Coroner. Bill's family, associates and Counsel were present, and Ana made it clear that the court was not allocating blame, but answering the points and questions above. This clearly caused some frustration, particularly for Nancy, and one of the key learning points of this exercise is that a simple apology goes a long way – once the facts were stated and recorded, it was apparent that there was no intent to harm Bill, he might have died anyway but earlier informed intervention, without judgement may have led to better treatment (head scanning and draining of a missed subdural haematoma). There were other lessons to be learnt as well – for example mention was made of a TAB alarm - incorrectly set up and used, as well as the lack of a proper falls risk assessment - relying on a device to stop a fall.

Key lessons learnt for those attending real court cases

- Be open and honest and if mistakes have been made acknowledge the same;
- If it isn't documented then the Court is likely to find that it did not happen;
- Try to make your statement as detailed as possible as this may mean that the Coroner reads your evidence rather than asking you to attend Court. If you are required to attend Court a detailed statement puts you in the best position to give cogent and credible evidence;
- Take the process seriously and ensure that you have looked at the medical records etc.; you are attending a Court and the Coroner will expect you to be well prepared and, if needs be, deal with matters that do not appear in your statement;
- Remember that the family is at the heart of the Coronial process – an apology or offering condolences can make a big difference to whether the family pursue a civil claim following the inquest;
- Prepare your statements on time and if not let the Coroner know that you are in difficultly in advance of the expiry of the deadline otherwise you may incur a fine;
- Don't panic – it is inevitable given your profession that you will at some stage end up giving factual evidence in a Coroner's Court. The Court is not there to attribute blame, it is a fact finding tribunal.

My thoughts to conclude:
Firstly, thank you to the organisers for giving us this excellent experience. Ana has said she will assist other organisations in setting up their own mock inquests; I think the value of the event as stated above make it a very worthwhile activity, one requiring a little bit of organisation and some creativity in adapting or writing the background story and characters.

IV Medication Errors:
The Clinical Evidence

Intravenous medication errors: background

The National Patient Safety Agency (NPSA) defines a medication error as "an incident in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether any harm occurred or was possible."[1]

Intensive care nurses spend nearly a third of their shift undertaking medication-related activities,[2] and the preparation and administration of intravenous (IV) medication is arguably one of the most challenging jobs they perform. Multi-tasking is common during medication-related activities and its complexity is challenged by frequent interruptions,[3] which have been shown to be directly associated with the rate and severity of medication administration errors.[4]

An estimated 58.8% of patients in hospital receive medication via the IV route,[5] meaning that every hospital has huge potential for IV errors. Errors due to infusion pumps are always high on the list of medical device incidents reported to the NRLS every year[6], and around 200,000 infusion sets are used annually in a large NHS Trust.

Intravenous medication safety has long been on the NHS agenda but remains a cause for concern (see Box 1). Today's NHS has three key areas of focus relevant to IV medication use (see Box 2):

- Ensuring safe and efficient IV medications management
- Standardisation of infusion protocols to reduce variation in care
- Ensuring operational - and cost-efficiency to minimise costs related to preventable adverse drug events

So, what IV medication errors are currently occurring, and how can it be improved to maximise patient safety?

Frequency, types and implications of IV infusion errors

IV administration is a frequent contributor to medication errors because:

- The inherent complexity of the multiple-step IV infusion process makes this particularly susceptible to errors; a meta-analysis of 16 UK studies found that IV administration errors were five-times more frequent than those associated with non-IV routes[21]
- IV medication is prescribed frequently during hospitalisation in around 58.8% of patients[5]
- IV administration often involves administering high-risk (high-alert) medications to high-risk patients

Indeed, errors occur frequently. According to NICE (2013), the National Confidential Enquiry into Perioperative Deaths report highlighted that a significant number of hospitalised patients were dying as a result of infusion of too much or too little fluid.

Box 1. Key IV medication safety documents and policies

- 2003; National Reporting and Learning System (NRLS) set up to encourage and promote a culture of adverse event reporting, including anonymous incident reporting[7]
- 2004: Department of Health published 'Building a safer NHS for patients: improving medication safety'[8] that stated "Proper application of procedures, checks and defences in the process up to the point of administration will ensure that the right patient receives the right drug, in the right dose, by the right route, at the right time."
- 2007: NPSA published 'Promoting safer use of injectable medicines' recommending "an exemplar standard operating procedure for prescribing, preparing and administering injectable medicines," and "use… dose checking software in 'Smart' infusion pumps and syringe drivers."[9]
- 2010: UCL Hospitals 'Injectable medicines administration guide' included information to support prescribing, dispensing and administration of intravenous, subcutaneous and intramuscular administration[10]
- 2013: NICE issued guidance on IV fluid therapy in adults including general safety principles[11]
- 2014: MHRA issued a Stage Three: Directive Patient Safety Alert to improve medication error incident reporting and learning, stating "…further improvements are needed to increase the number of incident reports, improve data quality and maximise what is learned from medication errors." NHS England mandated the introduction of medication safety officers and medical devices safety officers in all hospitals.[12,13]
- 2015: EMA issued 'Good practice guide on risk minimisation and prevention of medication errors', stating "Medication errors present a major public health burden and there is a need to optimise risk minimisation and prevention of medication errors through the existing regulatory framework."[14]
- 2016: Institute for Safe Medication Practices (ISMP) issued guidelines for safe implementation and use of smart infusion pumps.[15]
- 2016/2017: NHS Outcomes Framework, Domain [5] focuses on 'Treating and caring for people in a safe environment and protecting them from avoidable harm'[16]
- 2017: WHO Global Patient Safety Challenge aims to reduce the level of severe, avoidable harm related to medications by 50% over 5 years, globally[17]

The report recommended that fluid prescribing should be given the same status as drug prescribing. It also noted that, although mismanagement of fluid therapy is rarely reported as being responsible for patient harm, it is likely that as many as 1 in 5 patients on IV fluids and electrolytes suffer complications or morbidity due to their inappropriate administration.[11]

What is the number of IV medication errors in your hospital per year?

In a review of hospital units in Germany, the administration of IV medicines had an error rate of 49%.[22] In a prospective observational study of 107 nurses preparing and administering 568 IV medications on six wards across two teaching hospitals in Sydney, Australia, of 568 IV administrations, 70% had at least one clinical error and 26% of these were serious.[23] In a review in the UK on two wards in a teaching hospital with a ward pharmacy service:[24]

- The number of observed preparations was 77; the preparation error rate was 22% (95% confidence interval: 13-31%)
- The number of administrations was 63: the administration error rate was 27% (95% confidence interval: 16-38%)

Results from the multinational Sentinel Events Evaluation (SEE) study of patient safety in intensive care have shown medication errors are common in ICUs, occurring at a rate of 74.5 events per 100 patient days.[25]

A meta-analysis of 16 UK studies found that IV administration errors were five-times more frequent than those associated with non-IV routes[21]

Errors can occur at any stage of medication process (prescribing/ordering, transcription, dispensing/ transportation, and administration); however, in one study, 34% of preventable adverse drug errors occurred in the administration phase.[26] Administration errors are the hardest to intercept (0% intercepted at the administration phase vs. 48% intercepted at the ordering phase), with obvious potential harmful consequences for patients.[26]

In terms of administration, wrong infusion rate is a common error. This occurred in 21% of infusions given by nurses in PICU/NICU in a Belfast hospital (rate of clinically significant errors reported as 3.3%)[27] and in 48% of patients in a prospective audit in UK hospitals.[28]

In the recent ECLIPSE (Exploring the Current Landscape of IV Infusion PracticeS and Errors) study,[29,30] errors and discrepancies in IV practices with infusion devices were assessed in 16 hospitals in England. Preliminary data from 1,124 patients receiving 1,739 infusions in 14 hospitals has shown that 71% of patients (1,234 infusions) did not receive infusions from smart pumps [see later]. Smart infusions were associated with a trend (non-significant) towards a lower rate of errors compared with all other infusions. Of these, 11% were reported as errors in administration (vs. only 7.5% with a smart pump) and 50.8% as non-compliance with hospital policy. There were 1.3% (23 events) that were considered to be potentially harmful. The authors noted that only 10 of the 14 hospitals used smart pumps, and almost 40% of all smart pump infusions did not have appropriate drug library entry.[30]

Box 2. **Key publications supporting safety, standardisation and efficiency in IV medication use**

- Care Quality Commission (CQC) quality assessment – states that all care must be safe, effective, responsive and well-led[18]
- Dalton review – commissioned by the Health Secretary in February 2014 to explore options to "reduce variations in clinical standards, financial performance and patient safety". The principle guiding the review is that all patients should expect to receive the same high standards of care, anywhere, in any setting[19]
- Carter review – recognised the impact of unwarranted variations on the operational productivity and performance in English NHS acute hospitals (estimated to be worth £5bn in terms of efficiency opportunity) by utilising digital technology and information systems, and by standardising processes to release staff capacity[20]

Clinical and economic burden of IV administration errors

Critically ill patients are at high risk for adverse drug events for many reasons, including:[31]

- Complexity of their disease that creates challenges in drug dosing
- Vulnerability to rapid changes in pharmacotherapy
- Intensive care environment providing distractions and opportunity for error
- Administration of complex drug regimens
- Numerous high-alert medications received
- IV mode of drug administration

Exact evidence of the clinical and economic burden associated with IV administration errors is limited,[12] suggesting this could be a hidden problem. The National Reporting and Learning System (NRLS) receives large numbers of patient safety incidents from the NHS involving the unsafe use of injectable medicines, and some of these incidents cause death or serious harm to patients (see: https://report.nrls.nhs.uk/nrlsreporting/).

Available European studies suggest that, out of all observed infusion-related administration errors, up to 29% may result in potentially serious consequences for adult and paediatric patients.[23,32-34] It has been estimated that the probability of making at least one medication administration error in IV doses is 73%.[35] An in-depth NRLS review found that incidents involving injectable medicines represent 62% of all reported incidents leading to death or severe harm.[1]

A study conducted in a surgical ICU in Spain (1997-1999)[36] demonstrated an additional length of stay of 2.3 days for patients experiencing an adverse drug event compared with patients who did not have an ADE. An even greater increase in length of stay of 4.8 days was observed for patients having an IV administration-related adverse drug reaction compared with controls in an adult ICU at a US-based academic institution (although no substantial increase in length of stay in ICUs in a non-academic US institution).[37] A NICE 2013 costing review of IV fluid therapy in hospitals[38] noted that patients with complications appeared to spend an additional 2.5 days in hospital compared with patients without complications.[39] The impact of adverse drug events on length of stay is more significant in critically ill patients than those on a general ward, with an extra 1.6 days compared with general care unit patients in one US-based study.[40]

Clearly, IV medication errors are associated with an avoidable cost to the NHS and the patient. For example, extended hospital stays resulting from IV infusion errors will increase bed occupancy/cost. However, the true cost of IV medication errors is not known.[41] In one study that included UK hospitals, the cost of an IV administration error has been approximated to be €7,344, although this is acknowledged to be an underestimation of the true economic burden of errors.[42]

The cost per day in ICU varies in Trusts, depending on the exact nature of the stay[43] and has no specific HRG Tariff associated with it.[44] Recent data (2016) suggest that a Level 3 Intensive Care bed costs an average of £1,932 per night.[45] This means that up to £9,273.60 could be saved per patient by avoiding intravenous medication errors.[37,45]

> As many as 1 in 5 patients on IV fluids and electrolytes suffer complications or morbidity due to their inappropriate administration.[11]

The cost of adverse drug events involving IV administration of medications in critically ill patients was quantified as $7,935 in 2010 currency at a US-based academic institution.[37] Interestingly, these same additional costs were not observed for IV-related adverse drug events at a non-academic institution. In another study conducted in a New Zealand paediatric/neonatal ICU (2002 data),[46] the total cost of adverse drug events per year, adjusted to 2009 US currency, was $204,595, with $128,984 from preventable adverse drug events and $75,611 for non-preventable adverse drug events.

In a more recent study on a paediatric ICU, it was estimated that €172,279 was saved over 17 months by preventing adverse events after implementing Guardrails™.[47] IV infusion error-preventing interventions, particularly with high-alert medications, should be an essential part of enhancing patient safety.[1] The considerable clinical and ecomonic burden associated with errors means this issue should be reviewed, audited and addressed in all Trusts.

How dose-error reduction software (DERS) can reduce IV infusion errors

Intravenous infusion pumps that deliver parenteral medications at precise rates or in specific amounts and alert users to potential errors are often referred to as 'smart' pumps.[15] In 2004, dose-error reduction software (DERS) became available on smart pumps to further ensure that IV medication is administered as intended, within safe limits.[48,49]

DERS allows an organisation to create a library of medications that provide medication dosing guidelines, by establishing concentrations, upper and lower dose limits, and clinical advice.[15] Typically, the drug library can be adapted to each clinical area within a hospital, to reflect variants in drug dosing across different patient groups. The rationale underlying this technology is that IV drug administration errors can be minimised or prevented and, therefore, represents an important advance in patient safety at the point of care.[48]

Data captured and stored in smart infusion pumps provides a window into clinical practice. Thorough analysis of these data can result in the refinement of the drug library, as well as contribute to positive changes in practice.[15] A key part of successful implementation of a DERS system is the training of the clinical staff who will be using it on a day-to-day basis.

Summary

In today's healthcare environment, priorities include:

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

Using DERS throughout the hospital, helps to ensure safe and efficient IV medications management, reduced dosing errors, standardises infusion protocols, reduces unwanted variation, and minimises costs associated with preventable adverse drug events.

Intravenous medication errors are a risk for the safety of hospitalised patients, in particular during the administration phase. Infusion devices with safety features, such as dose error reduction software (DERS), intercept IV medication administration errors by creating alerts when a deviation from a standardised IV protocol might occur.

The WHO Global Patient Safety Challenge aims to reduce the level of severe, avoidable harm related to medications by 50% over 5 years, globally.[17] Using DERS on all wards will help to achieve this and other NHS targets, thereby helping to improve patient safety and cost-efficiency of care.

To request a copy of BD's Medication Errors Clinical Summary, please email **UK-Marketing@bd.com**

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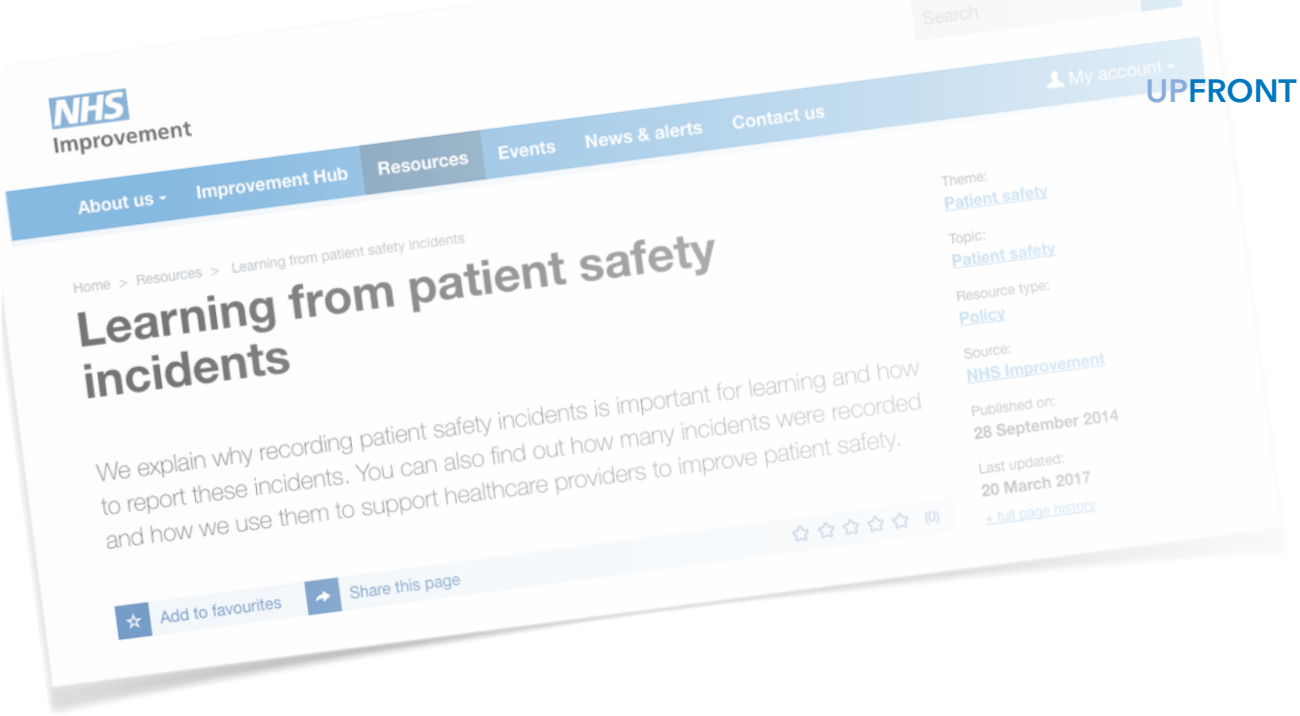


THE MEDICAL DEVICE SAFETY OFFICER (MDSO)

As a Medical Device Training Manager working in Morrison Hospital in Swansea and NAMDET Chairman, Paul Lee explains the Medical Device Safety Officer (MDSO) role and how the network helps contribute towards incident reporting and learning

We aim to avoid harm, but when a patient is harmed or could have been harmed due to an incident involving a medical device, it is vital that it gets reported to help improve patient safety. In March 2014, to improve medical device incident reporting and learning, NHS England and the MHRA issued a joint patient safety alert asking providers to identify a named Medical Device Safety Officer (MDSO). A Stage 3 Directive was issued from NHS England and the MHRA, asking people to improve medical device incident reporting and learning.

Since then, NHS Improvement has gone on to develop an interactive and learning website, where all incidents can get reported and lessons can also be learnt. **https://improvement.nhs.uk/resources/learning-from-patient-safety-incidents**

The Medical Device Safety Officer Network consists of two key parts. Medical devices are covered by the Medicines and Healthcare Regulatory Agency, the MHRA, and patient safety issues in the United Kingdom are looked at by NHS Improvement. Patient care is delivered by NHS providers and reported incidents are collated via the National Learning Reporting System (NLRS) which records approximately two million incidents per annum. Within their organisations, the role of the Medical Device Safety Officer is to promote safe use of medical devices to encourage incident reporting at all levels across the organisation, to provide expert advice for those asking for help, and to serve as the essential link for identification of risks and concerns surrounding medical devices. They also have an important role in supporting the implementation of local and national safety initiatives such as patient safety alerts and notices.

Key to the success has been building a community, and we currently have representation from all countries across the United Kingdom that link into this network. Active participation is also important, and people get involved in different levels from contributing towards alerts to carrying out surveys. MDSOs also offer valuble insight. They usually have a range of experiences, from clinical engineering to medical device management, and know how these devices should or shouldn't be used, and that can help contribute towards outcomes from patient safety investigations. An important element of the MDSO network is the monthly WebEx meetings. Medical Device Safety Officers get together every month to review current issues, and they could literally be just a few days old, where we can share learning, ask for help and assistance and help MDSOs to take back important messages to their organisations. The Medicines and Healthcare Regulatory Agency and NHS Improvement Patient Safety also contribute towards these WebExs.

An important element of the MDSO network is the monthly WebEx meetings. Medical Device Safety Officers get together every month to review current issues

The role of an MDSO is, by definition, varied and currently within the UK there are 350 signed up Medical Device Safety Officers. They have discussed, debated and shared information around 40 key subjects since March 2014. If you wish to become an MDSO then there is a registration process and the vast majority of MDSOs are either Medical Device Engineers, Clinical Engineers, nursing staff, clinical governance staff or Medical Device Managers. To register, you need to be nominated by your organisation, and usually there is only one MDSO login per employer. Once registered, you can access the forums and safety alerts where you can discuss issues of concern, and get access to WebExs which are recorded monthly. You will also then be added to the national MDSO list and will receive an email each month on how to log into the webinar or the WebEx. MDSO's are also invited to the annual MDSO Patient Safety Conference, which happens in April each year. An additional resource that the MDSO network can link into is the new National Association of Medical Device Educators and Trainers, or NAMDET, who publish this journal.

BLOCKING CHANGE

In the early 2000s, the death of a nine-year-old boy led to a review of instances in which patients' breathing tubes had become blocked by a foreign object. An expert group reviewed the cases and concluded the design of certain plastic caps increased the risk of tubes becoming inadvertently blocked. Yet when it comes to a certain type of filter used for mechanically ventilated patients, the potentially dangerous design is still available. While national bodies work to address the situation, medical device safety officers (MDSOs) are being urged to take action at their organisations, as Claire Read reports.

It should have been a straightforward operation to deal with a relatively straightforward situation. Young Tony Clowes had fallen off his bike and in the process had cut off the top of his finger. The operation was designed to reattach his fingertip. But the nine-year-old died on the operating table at Broomfield Hospital in Essex, starved of oxygen due to a blocked breathing tube. It turned out that a plastic disposable cap had become lodged in part of the anaesthetic tubing.

When the coroner came to investigate the case, she noted with concern a very similar case at a nearby hospital. And so a criminal investigation followed Tony's July 2001 death, uniting police forces across the country in the concern that someone might be maliciously blocking breathing apparatus.

The investigation – dubbed Operation Orcadian – lasted a year. But the ultimate conclusion was that the deaths had all been tragic accidents, with small plastic items inadvertently becoming lodged in parts of the breathing circuit – and not being spotted until harm had either occurred or been narrowly averted.

And so attention naturally turned to mitigating the risk of such accidents ever occurring again. The then-chief medical officer Sir Liam Donaldson assembled a group to consider how to do just that. The Expert Group on blocked anaesthetic tubing was led by Professor Kent Woods, who would serve as chief executive of the Medicines and Healthcare products Regulatory Agency for almost a decade, and reported its findings in May 2004.

One of the group's major recommendations: that, wherever possible, disposable plastic caps be manufactured *"in brightly coloured material, preferably red, to aid visibility"*. The report continued: *"Where feasible, caps should be tethered rather than fully detachable."*

Quite simply, the aim was to make it very hard to miss a cap that had lodged itself in part of the breathing tubing – or, preferably, to ensure such a blockage could never happen because the cap was tethered.

Almost two decades on, though, and there is at least one piece of equipment that is not consistently adhering to these recommendations: HME filters.

Heat and Moisture Exchanger (HME) filters are crucial to preventing complications in patients who are on mechanical ventilation. When we breathe normally, air is filtered, warmed and moistened by the nose and the upper airway. But if someone is intubated or on artificial ventilation, that process obviously doesn't happen. To prevent damage and infection to the lungs, then, HME filters replicate the process – providing artificial humidification.

Look on the NHS Supply Chain website and you'll find a range of filters available. But what is causing concern at a national level is that some have plain white caps, which are in some instances untethered. The danger is exactly that identified in the 2004 expert group on blocked anaesthetic tubing report – that a cap could be misplaced, make its way into a breathing tube and go unnoticed.

During the September Medical Device Safety Officer (MDSO) WebEx, it was reported that NHS Improvement is working with the Medicines and Healthcare products Regulatory Agency (MHRA) and with the clinical and product assurance (CaPA) group at NHS Supply Chain to address the situation.

But for now, MDSOs are being asked to review arrangements in their organisations. Are all HME filters in your trust the type with a coloured, tethered cap? Who is responsible for procurement of the filters? Are they aware of the events of 2001 and 2004? The reality is that they may not be. But the families of those patients harmed by inadvertent blocking of breathing tubes will never forget – and rightly expect the NHS to adopt exactly the same position.

How we responded to the issues you reported

To accompany our bi-annual production of official statistics on incidents reported to the National Reporting and Learning System (NRLS), and using information received from other sources, we produce a regular Review and Response Report outlining how we used this information to improve patient safety.

Our latest report was published 25 September 2018, covering the period October 2017 to March 2018. It describes our process for reviewing incident reports and gives examples of the actual action we took as a direct result, whether by issuing a Patient Safety Alert or working with partners.

Our primary reason for publishing the report is as a thank you to all the staff, patients and members of the public who have taken the time to report incidents. By showing the difference their efforts have made, we hope staff across the NHS find the report both informative and inspirational; and that it encourages them to continue to report all incidents so that together we can improve patient safety and protect our patients from harm.

What we reviewed

Our review and response role starts with our clinicians reviewing information from a range of sources to identify new or emerging issues that may need national action.

This function is supported by registered nurses, with experience in patient safety relating to surgical, medical, community, paediatric, neonatal and mental healthcare, a midwife, pharmacists, a pharmacy technician and a physiotherapist; many of whom work on wider patient safety policy and projects as well as review and response.

Additionally, we use the skills and experience of expert patient safety advisors who combine working one day a week with us with clinical, educational or leadership roles as GPs, paramedics or in the care home, mental health or learning disability sectors.

In the six month covered by this report our clinical teams reviewed

9,991
Incidents reported to the NRLS with an outcome of death or severe harm (including reviewing each update of these incident reports)

4,257
Selected categories of Serious Incident reported to StEIS (new or under-recognised review)*

519
NRLS incidents from areas of special focus (currently inclusing all GP eform repors of moderate harm, all anaesthetic eform reports)

236
Potential and confirmed Never Events reported to StEIS*

39
Incidents reported to the NRLS by patients or the public (we review all these even if not reporting harm)

22
Regulation 28 letters (letters from coroners where they have identified a need for action to prevent further deaths)

Where any of these sources suggest there could be a new or under-recognised issue that requires national action we explore further. Although our process is often triggered by a single patient safety incident, from that point onwards we work to understand the patient safety issue. We do this by looking to identify a wider pattern in other similar incidents reported previously, including no harm 'near miss' incidents – and we focus on what could go wrong in future.

Of the incident reported, and the other sources we reviewed between October 2017 and March 2018, our clinical teams identified 85 issues to take forward for potential national action. We then worked with frontline staff, patients, professional bodies and partner organisations to decide if we need to issue advice and guidance to reduce risks, via a Patient Safety Alert, or if we can influence or support other organisations to act upon the issue.

What action did we take around medical device issues

The Review and Response Report covers not only the alerts we issued but case studies on how we worked with other organisations during the set timeframe, as well as the issues discussed through the MDSO monthly WebEx and forum. You can read the full report on the NHS Improvement website but some examples relating to medical devices are below:

Patient Safety Alerts

Confirming removal or flushing of lines and cannulae after procedures

Issued: 9 November 2017

This alert asked providers of NHS-funded care that undertake surgical interventions or other procedures involving anaesthesia or intravenous sedation to amend the Sign Out section of the WHO Checklist, or equivalent in local use. It should include confirmation that before a patient leaves the procedural area cannulae and intravenous (IV) lines have been removed or flushed, and this action should be documented.

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

Issued: 9 January 2018

As previously reported in the MDET journal, this alert asked providers that use oxygen cylinders to determine if immediate local action is needed to reduce the risk of incidents involving staff being unable to obtain and continue flow from oxygen cylinders.

Issues where we advised or influenced others on action

Medication via nasogastric tube in unconscious cardiology patients

An incident identified through our regular review of Never Event reports described a patient who needed emergency treatment following a cardiac arrest. The patient had been intubated and urgently needed dual antiplatelet therapy (DAPT); a nasogastric (NG) tube was inserted to allow administration. After DAPT had been administered the NG tube was identified to be in the patient's lung. The essential checks of NG tube placement had not been done.

Together with the British Cardiovascular Society we have developed guidance that reinforces our earlier advice on confirming NG tube placement and provides information on alternative intravenous or rectal antiplatelet medication for unconscious patients in whom NG tube placement cannot be safely confirmed.

Risk of harm from ophthalmic cannula detachment during surgery

MHRA contacted us about a small number of incidents of ophthalmic cannula detachment during ophthalmic surgery. The ophthalmic cannula is attached to a syringe and when pressure is applied to the plunger can produce significant hydraulic force. Should the cannula detach, it will do so with an intensity that can cause injury and visual impairment.

An NRLS search for a two-year period identified 23 incident reports of cannula detachment during an ophthalmic procedure. Reviews by MHRA concluded cannulae were detaching because of how they were being used rather than a design issue with the equipment concerned. MHRA issued a short safety message via the MDSO network advocating that only Luer lock syringes should be used in ophthalmic surgery and only after their secure connection has been checked. We asked the Royal College of Ophthalmologists to disseminate the information from MHRA and the NRLS through its networks.

Entrapment due to bed/bedrail/mattress incompatibility; assessing 'hybrid' mattresses

Our regular clinical review of Serious Incidents reported to StEIS identified an incident of entrapment involving a patient in the community and a 'hybrid' mattress (in a healthcare context, this is a mattress that can be switched between foam and alternating pressure modes). The mattress appeared to compress to such an extent that the patient was able to thread their legs between the mattress and the lower rail of the bedrail. This incident suggested that the need to assess hybrid mattresses twice – in both their standard mode and alternating pressure mode – might be under-recognised.

We shared this information with the MDSO's network, MHRA, to inform any future updates of its guidance, and the National Association for Safety and Health in Care Services, which has agreed to share key learning messages with relevant forums such as the National Association of Equipment Providers.

Risk of bowel perforation when self-administering rectal irrigation

We identified an incident where a patient sustained a perforated bowel while self-administering trans-anal irrigation. Such specialist systems are used to manage chronic bowel dysfunction and patients, carers and staff need specialist training in their use.

We were concerned that the risks of harm are not always fully appreciated. We asked MHRA, who had previously published a medical devices alert on a trans-anal irrigation system, to review company training guidance manuals and instructions for use, to ensure risks were adequately described.

We also brought our concerns, and MHRA's alert, to the attention of NICE; who plan to update its medical technologies guidance (MTG) development processes to ensure any relevant alerts are included.

Maintenance of 'critical to life' medical devices in patients' own homes

Following concerns raised by a patient, we reviewed incidents involving problems with maintaining or servicing 'critical to life' medical devices in patients' own homes. As these devices can be used in the patient's home for prolonged periods, sometimes for the rest of their life, they may require different maintenance and servicing arrangements from most medical equipment issued for use in the home; which is typically used for shorter periods before being returned to an equipment store.

The National Association of Equipment Providers, the Institute of Physics and Engineering in Medicine and the National Performance Advisory Group agreed to share our findings with their members and reinforce the requirement to give 'critical to life' devices a particular focus in their equipment provision systems.

Alternating pressure system mattress and fire risk

We became aware of reported incidents of patients not being issued an alternating pressure system (APS) mattress for pressure ulcer prevention because healthcare professionals believed APS were banned for patients who smoked. This belief is likely to have come about because air circulation in APS mattresses is pump driven, and if a cigarette burn penetrates a mattress, air escaping from the puncture could accelerate any fire. However, this risk must be weighed against the patient's risk of developing a pressure ulcer, and any other factors that might increase or reduce the risk of fire in their environment.

The Tissue Viability Society, the Stop the Pressure Programme, the Royal College of Nursing District Nurse Forum and our patient safety advisor for care homes all agreed to share this information with their professional members.

Risk of air embolus when inflating radial artery compression device

We identified a serious incident in which air was injected into a patient's circulation during removal of a sheath from their radial artery.

Radial artery sheaths are commonly used in angiography procedures and inflatable compression devices may be used to prevent bleeding when they are removed. The device is inflated over the insertion site of the sheath using an air-filled syringe and compresses the radial artery to stop bleeding. In the reported incident the air was mistakenly injected via the radial artery sheath into the patient's circulation.

We asked MHRA to investigate whether equipment design may have contributed to the error. This revealed that the inflation syringe provided with the compression device had a Luer lock, which can be connected to arterial sheaths. The manufacturer has now withdrawn the Luer lock syringes in the UK and they will be phased out across the European Union in 2018.

Ambulance tail-lift failures

We identified an incident that raised safety concerns about emergency ambulance tail lift hoists. As tail-lift hoists are being used in emergencies, any problems with their operation could delay treatment for critically ill patients.

Reported problems appeared to have occurred with a less commonly used tail lift system which was integrated with a specific vehicle design; which has advantages in certain operating environments. Extra training has been made available to users of this design. Our findings will inform wider work on standardisation of emergency ambulances design across England.

Enhancing operator skills for the Lifepak 15 monitor/defibrillator

We identified a small number of incidents involving the Lifepak 15 monitor/defibrillator during resuscitation episodes. These raised several concerns, involving capnography monitoring, switching on and off and changing functions rapidly, and switching from automatic to manual mode. Incidents had been appropriately reported locally and investigations undertaken, including by MHRA, but no technical faults were found with the devices.

We worked through several clinical scenarios, with a clinical instructor at an ambulance service training college, designed to test each of the concerns and concluded that the problems did not stem from device functionality and could best be addressed with training focused on the specific device. Other ambulance trusts, that use Lifepak 15 monitor/defibrillator device, have used these findings to change their approach to training.

Using anti-syphon valves during intravenous infusion therapy

We identified a serious incident in which a patient, who was accidentally given more potassium chloride than intended, sustained a cardiac arrest. The patient was receiving fluids through a gravity IV administration set and potassium chloride through an infusion pump. Both infusions were flowing into a central line which was inadvertently clamped, stopping all fluid going into the patient. As the potassium chloride in the infusion pump was being given under pressure, it tracked up into the administration set attached to the gravity IV bag. When the central line was subsequently unclamped, the patient received a rapid infusion of the potassium chloride that had accumulated in the gravity IV administration set.

Accepted and routine practice is to use anti-syphon valves when these two types of infusions are combined. We shared our findings with the Safer Anaesthesia Liaison Group (SALG) and it was confirmed that the labelling of anti-syphon valves contributes to these types of incidents as, when removed from their packaging, they look very similar to one-way valves and connectors. It considers this similarity in appearance means staff mistakenly believe an anti-syphon valve is in place. MHRA will consider how they can work with relevant partners to make it clearer what a device is by labelling the actual devices.

Want to find out more

You can read the full Review and Response Report – October 2017 to March 2018, as well as previous reports on the NHS Improvement website **https://improvement.nhs.uk/resources/patient-safety-review-and-response-reports/**

THE ASSOCIATION OF PERIOPERATIVE PRACTICE

TOGETHER IN EXCELLENCE: BUILDING ON 60 YEARS OF PATIENT SAFETY

THE ASSOCIATION FOR PERIOPERATIVE PRACTICE'S (AFPP) VISION IS TO 'LEAD PERIOPERATIVE EXCELLENCE' THROUGH FACILITATION OF EDUCATION, DETERMINING STANDARDS, PROMOTING BEST PRACTICE AND NETWORKING. ALL OF THESE ELEMENTS COME INTO PLAY AT OUR ANNUAL RESIDENTIAL CONFERENCE WHICH IS HELD AT THE UNIVERSITY OF YORK EVERY AUGUST.

Our plan for 2018 was to grow our delegate footfall by offering the event at the moderate day rate in support of our charitable requirement to provide good quality education at an affordable price. As ever the HQ team worked hard to ensure that everything was in place to support the 390 plus delegates at the York campus. Our remit was to empower everyone to go back to their workplace and distribute their energy, share their experiences and communicate how fabulous the 2018 Residential event had been and what an amazing organisation we are.

The themes this year covered never events, the surgical count, managing change and culture, risk management, undermining and bullying, the freedom to speak up, HR and retention strategies, surgical site infection, leadership, kindness, cell salvage, recovery, the WHO checklist and root cause analysis, patient warming, difficult airway management, theatre utilisation and pre-op assessment.

Penny Haslam, our opening keynote speaker, a former BBC TV and radio business presenter had required huge amounts of confidence throughout her career. However, often confidence had let her down and as such she is fascinated by it. Why does it come and go and what can we do when we face situations that cause us self-doubt, indecision and stress? Penny's session was both inspirational and humorous. She used her 'five steps' model to build unshakeable confidence to empower the audience to deal with difficult situations within their work place and achieve excellent results. We looked at how behaviours can challenge effectiveness, different personalities within teams and how we can unleash the power of our own emotional intelligence.

Our second key note speaker was Matt Lindley from Propel Performance, he closed our first day with an amazing talk on resilience, understanding team members and investing in people. He provided insight into how leaders can use empathy to support team members and understand the issues they are facing and help them achieve a high level of performance in the workplace.

On Saturday Adrian Jones, President AfPP, introduced our Daisy Ayris lecture speaker, Prof Derek Alderson, President RCS England. He embarked on his session which looked at the theatres of the future, where an holistic approach to surgery could provide a better understanding of patients' needs. He discussed integrated operating rooms, robotic systems and four new systems currently being developed and how he envisaged them becoming the way of working in the next 10 years. He talked about the ethical issues of tissue engineering and how any team was only ever as good as the weakest link in the chain, therefore reinforcing the importance of team work, human factors and good communications.

Our closing session looked at how we can boost our FAB Quotient for sustained energy and resilience. Celynn Morin, dietician, speaker, author and French foodie, provided us with the opportunity to stop and think about our personal wellbeing, something we rarely get the opportunity to do. Her knowledge of her subject and insight into managing our own health was excellent. We all went away with a pledge of one small thing that we were going to change.

This meant that we had undertaken a 360-degree loop finishing with the opportunity to evaluate how well we look after ourselves rather than our usual mantra of us focussing on patient care. It was refreshing to say the least.

The conference also gave us the opportunity to launch our new training video – Peter the Perioperative Patient and the Perioperative Journey. An animation developed to support education and training, with key learning opportunities, highlighted by 'light bulb' moments, so that the animation can be stopped at key points for education to be delivered around particular areas of expertise. The animation is available under the resources section of the AfPP website: www.afpp.org.uk
The event culminated with a Masked Ball. Our medical device partners did not disappoint and provided their ongoing support to our organisation, some of them have been with us since the NATN days. There are great opportunities for our members to received funds for their education or research requirement. Please look at the AfPP website for more information.

There were masks, merriment, mentoring and many models of excellence discussed to support all practitioners in their day-to-day practice. No matter where they may be on their perioperative journey the residential event supports them with many CPD requirements. The whole weekend proved yet again that theatre practitioners love an opportunity to learn, which we are able to provide and they take their careers very seriously but when it comes to partying ……..
well, what can I say!

Dawn L Stott
Chief Executive, AfPP

Article by Diane Irvine,
CEO of Healthcare Skills International

When education and training are last on the list

We know that sometimes education and training are last on the list of a busy Hospital's priorities. We all know that things go wrong. We know that frequently there is no time and no budget for training and in the middle of a hectic hospital department and sometimes there is no motivation or appetite for it either.

Yet, we are also acutely aware that training is a legal requirement for hospital staff (employers' liability) and underpins every role.

The fact is, training is essential and an integral part of every hospital role. Training and roles are NOT mutually exclusive.

Hospitals have to ensure that training time – not just the duration, but the frequency of training, the scheduling and timing of training – is considered important enough to be a priority.

Training managers and staff need to be allowed dedicated time for training or dedicated audit days as well as allocated protected time for online learning, together with certification opportunities via CPD or similar accreditation programmes.

We know that people may be UNMOVED to change their clinical practice or use new technology because of the restraints of time and resource. However, there are also those who actively avoid training because they are:

- **UN-aware**
- **UN-informed**
- **UN-trained**
- **UN-available**
- **UN-motivated**

To address these "UNs", as hospital trainers it is necessary to reframe "education and training " as defining the optimal patient journey.

IF UN-aware

If you have the responsibility for training, then you have to discover and confirm WHAT the staff need and HOW they need it addressed, a good old TNA (training needs analysis).

IF UN-informed

Sometimes we don't know what we don't know. Or we don't fully understand what we don't know (yet). This is evident even in the mandatory training topics such as child protection, fire safety, new job induction or code of conduct.

In-service product training for hospital staff is not listed as mandatory, but in the interests of patient safety, and to avoid negative outcomes due to mis-use, product training is highly recommended and should be mandatory.

Most medical errors involving medical devices are not caused by mechanical failures. For CE-marked products, the requirement on the company to provide product training and support is mandatory (ISO 14971, 13485).

For hospitals, it is the employer's liability legislation that sets out that the employer (the hospital) must provide staff with the necessary, relevant education and training that they need to safely and effectively carry out their contracted roles. This takes us back to the earlier point above that training is intrinsic to staff roles and should not be an add-on.

IF UN-trained

In delivering education, then train to educate. Access courses to train the trainer, such as PGCE , Post Graduate Diploma in Clinical Education are available to everyone.

IF UN-available

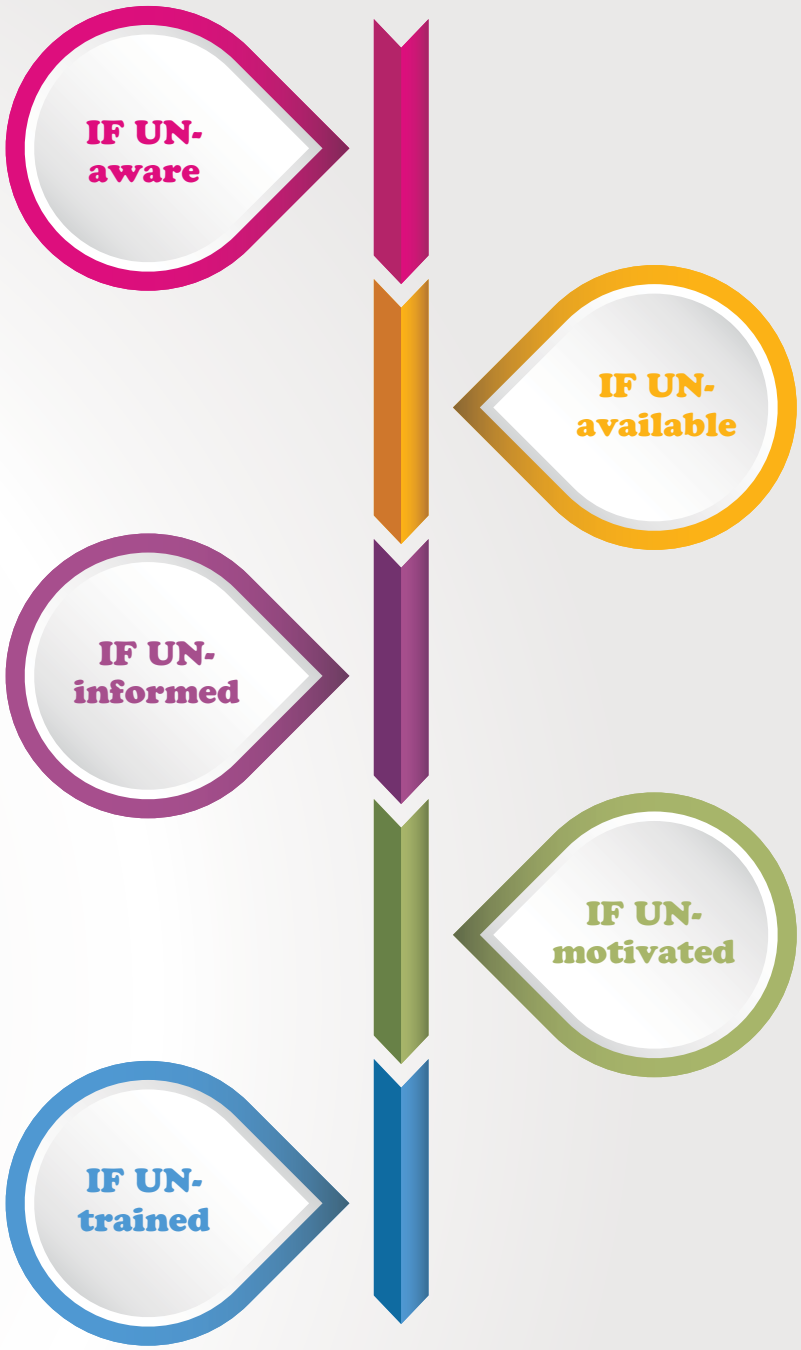
In these instances, there will typically be evidence of deliberate avoidance of training. Here it is helpful to consider all possibilities before jumping to a conclusion – it may be due to a customer/patient complaint or a difficult, challenging programme.

For online training, it might be due to a variety of factors, such as lack of skills, dexterity for typing or underlying learning needs such as dyslexia, colour blindness or Attention Deficit Hyperactivity Disorder

IF UN-motivated

Interest and engagement may need to be developed. Even with Compliance, hospitals are struggling to resource training. For example it is not feasible for one Professional Practice Development manager to organise training for all hospital staff for Fire safety, CPR (ILS) and to achieve this annually even though this is what Compliance specifies. This alone would demotivate the most engaging of trainers. As for the staff they need to understand in no uncertain terms the reason WHY they have to complete this training. Understanding of neuroscience and adherence to factfulness will help trainers to do this. Using neuroscience and brain friendly approaches allows trainers to focus on the relevant information at the right time.

In any training situation, the goal is optimal knowledge/skills transfer without "brain overload".



So, having "their brain in mind" will motivate your trainees and result in better knowledge transfer, decision-making, a greater understanding of patients' requirements and an enhanced ability to interact with colleagues in clinical teams.

Situational awareness, external engagement, communications leadership, relationship influencing and "inner and outer improvement" are some of the core principles to be applied in the delivery of your content. Our brains have tremendous capacity to learn. How training is delivered and the learning environment in which it is delivered impact on the mental capacity to transfer newly acquired knowledge and skills.

"Brain friendly" changes to the way training is delivered can improve the opportunity for the transfer of learning. Having a better understanding of how the principles of neuroscience can turbocharge the effectiveness of the training that you deliver will result in a prophylactic rather than a therapeutic approach to training.

So.... no more "last on the list" for hospital staff training.
Promote the best clinical support, levels of training, technical support and demonstrate the highest standards of Best Practice for Patient Safety.

Next issue's article… How to turbocharge your training courses using Neuroscience and "brain friendly" techniques.

Selfie

Name: Marie Law
Role: Head of Medical Engineering and Device Governance
Hobbies / interests:
I love to sew – and hoard fabric. I also paint a bit and read a lot.

What is your working history that led to where you are now?
I qualified as a nurse in 1985. After about 15 years as a Ward Manager I wanted to work more predictable hours, to allow more time with my children. I moved anxiously into Clinical Education but found that I loved teaching and was very happy there with a brilliant team. About 7 years ago I was asked to help establish better documentation and training assurances for staff using medical devices. To do that successfully, I had to learn so many things about medical equipment, legislation, guidelines and so on. The new role was an opportunity to review and develop policies processes and procedures. I established good working relationships with the Engineering Managers and we began to interlink practices for safer device use. I had a ball. When my 2 year secondment was up, I stayed.

What are your responsibilities?
In my present role I provide a medical devices service delivery model that involves managing the biomedical engineering teams, medical device governance agenda and medical device training requirements

What do you feel distinguishes working in the Pennines compared to other areas across the UK?
Rainfall

What has been your most significant accomplishment in your work?
I think we were amongst the first NHS organisations to have a dedicated Medical Device Governance Team. This has enabled us to embed robust processes that have in turn provided a clear understanding of where our key risks and action points are. We have used these (and still do) to create a culture of continuous quality improvements for processes across all aspects of device management

What things about your work frustrates you the most?
I think it's similar for most people; so much that could be done but having to limit myself to those things that will provide the greatest benefit and impact.

What do you most want those working with medical devices in the NHS to understand?
That having a certificate of attendance doesn't mean that learning took place. Nor does declaring competence, by signing the bottom of a list of device types and models, provide assurance of anything.

What message would you like to give senior management in the NHS?
Good job!

With your NHS role in mind, what would you want to say to those negotiating the terms of Brexit?
Act wisely

Have the recent changes with regards data protection (GDPR) affected the way you work and how?
No. Things change all of the time in the NHS. We are aware of the new requirements, we review what we do in terms of data storage and collection and take action as necessary to comply.

Having attended a coroner's inquest, what piece of advice would you give others who may find themselves in the same situation?
Although no one is on trial, any inquest is likely to be full and frank in uncovering the factors leading to a person's death. When it's your turn, do not guess or make assumptions about what others did or might have done – stick to what you know from your own experience. If you do not know the answer – say so. Try to remember to acknowledge the family at the inquest. It is very stressful and upsetting for them too.

What changes would you like to see in the NHS relating to medical devices?
It's no secret that I would like to see all persons delivering medical device training hold a relevant accredited training certificate.

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

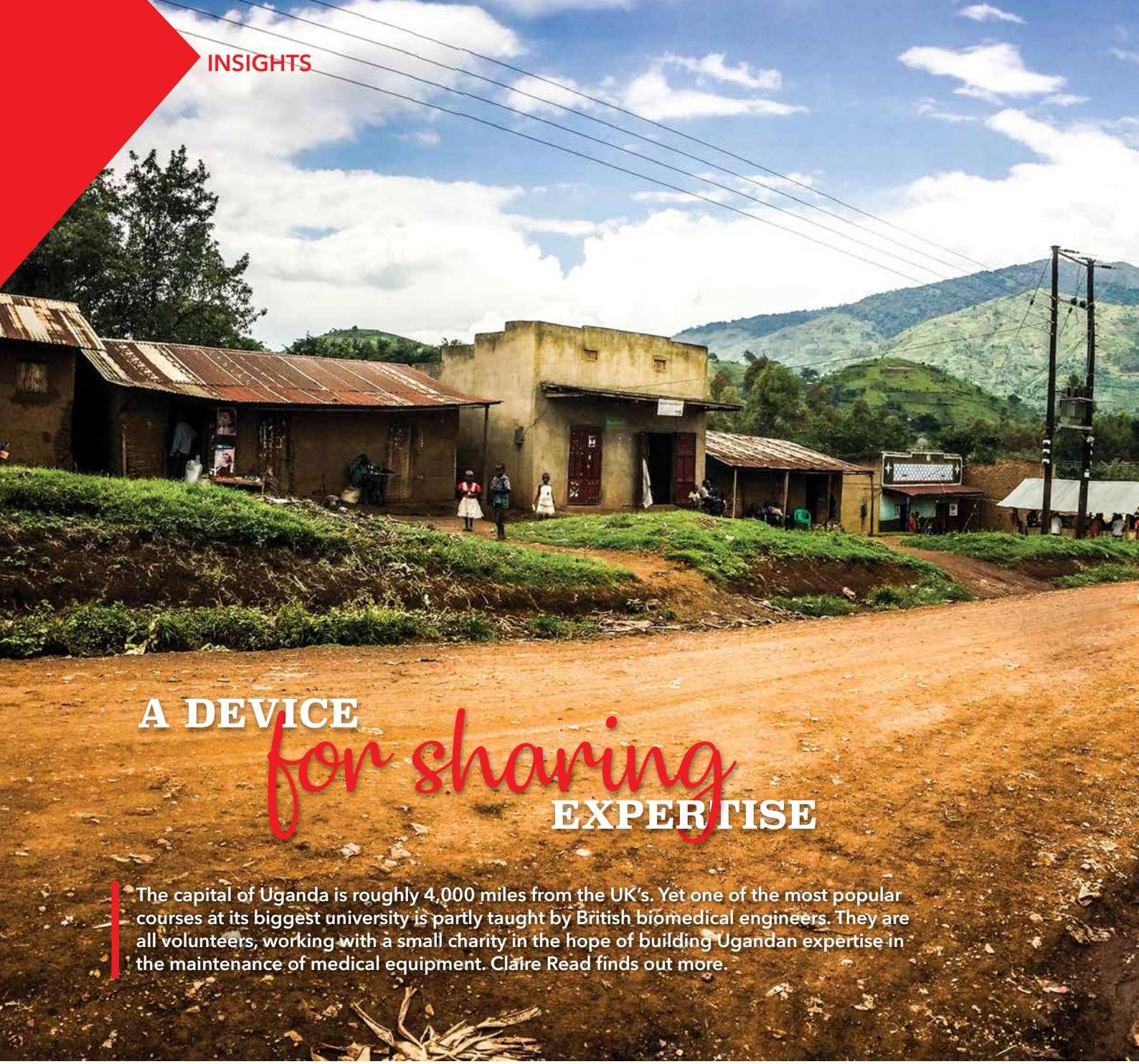
What topics would you like to see covered in MDET in the future?
MDET is a great, high quality resource. I would like to see more input from NAMDET regional groups and Chairs. I think this would help readers identify areas of interest or similar work streams to their own. It would encourage membership, networking and collaborative working.

If you could be any fictional character who would you be and why?
I would be Gertrude Bell - who was definitely not fictitious but was a brilliant scholar, shaper of nations, mountaineer, archaeologist and travel writer. I would love to have half her courage. And she had great hair.

If you were granted three wishes what would they be?
To be calorie resistant, able to time travel and be fond of housework.

What's your favourite book or film and why?
My favourite film is Sliding Doors. I would love to see how life would have emerged if I had made different choices – not that I would change much; just curious. I'm a Sagittarian so I always read the back of the book first.

What / who is the person or thing that has inspired you the most and why?
No one thing or person has inspired me most. I am the product of a million experiences and encounters



A DEVICE *for sharing* EXPERTISE

The capital of Uganda is roughly 4,000 miles from the UK's. Yet one of the most popular courses at its biggest university is partly taught by British biomedical engineers. They are all volunteers, working with a small charity in the hope of building Ugandan expertise in the maintenance of medical equipment. Claire Read finds out more.

In Eastern Kampala, surrounded by lush foliage and roads of red soil, lies Kyambogo University. One of the eight public universities in Uganda, it offers well over one hundred courses and has a student body that's around 25,000-strong. But in recent years, one study programme has gained particular attention: a diploma course which teaches graduates how to fix and maintain medical equipment.

Part of the reason it's captured attention is its tutors, a good chunk of whom come from a land where the foliage is typically a little less lush and the roads are grey rather than red – yes, you guessed it, the UK.

The presence of these tutors is down to a small Wiltshire-based charity by the name of the Amalthea Trust. Founded in 2007, its aim is to offer biomedical engineering training in less economically developed countries.

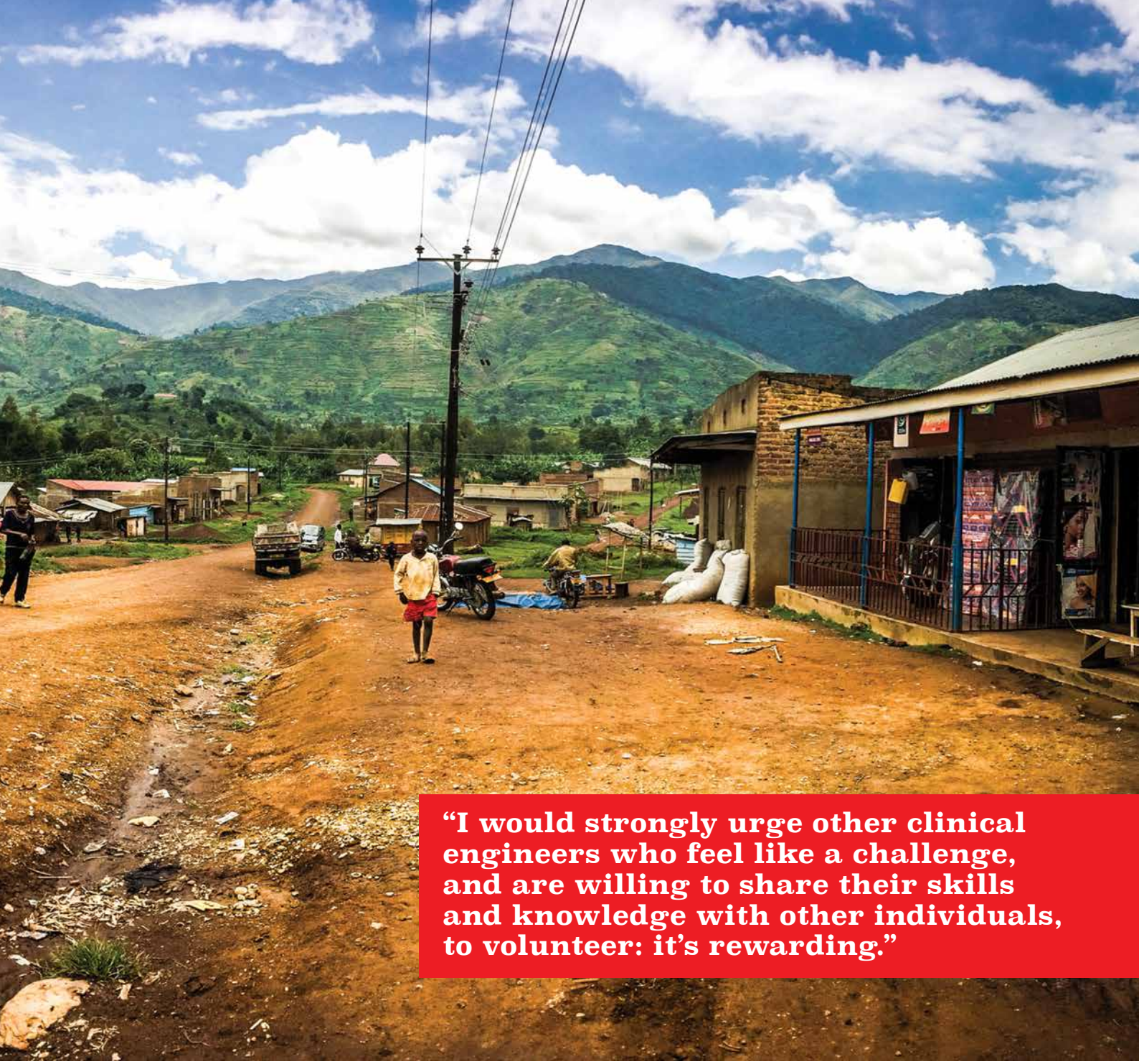
Because while many of us might assume the biggest problem with medical devices in such countries is a simple lack of them, the charity's programme director explains it's a little more complicated than that.

"To be honest, there's quite a lot of equipment in Uganda," says Martin Worster. *"When you go to hospitals, you see loads of stuff parked in corridors because they can't use it – either because they've not had any training in how to use it, or because something simple like a blown fuse has happened and they haven't got the engineers to fix it."*

It's this situation which the Amalthea Trust is trying to address. *"The big need in biomedical engineering courses in these countries is the practical side of things,"* explains Martin. *"Because to start with, they don't have the people with the practical experience to pass on."*

It was after the charity's initial project – helping to establish a biomedical engineering workshop at Mulago Hospital, the main referral centre in Kampala – that staff at Kyambogo University got in touch.

"They had a biomedical engineering diploma training course they'd just



“I would strongly urge other clinical engineers who feel like a challenge, and are willing to share their skills and knowledge with other individuals, to volunteer: it’s rewarding.”

established and they were looking for help with the practical element – so getting out a screwdriver, getting the back off a defibrillator, saying this is what you need to do to check for faults, these are the sort of things that tend to go wrong, this is how you maintain them, that sort of thing,” remembers Martin.

It was the genesis of a collaboration which has seen a total of around 30 NHS volunteers travel to Uganda to pass on their expertise. *“We do two six week semesters at Kyambogo; one in the Spring and one in the Autumn,”* explains Martin, who joined the charity after his retirement as a schoolteacher.

“We send out three volunteers for each semester, to do say two weeks each on a range of items of equipment.”

He continues: *“The most common pieces of medical equipment in Uganda are basic things like patient monitoring, incubators, there’s obviously a demand for them. There is a demand for x-ray and ultrasounds as well – ultrasounds is a big growth area, because of course portable ultrasounds can be bought relatively cheaply second hand.*

“We offer training on infusion pumps and syringe drivers as well, although there again in your average rural hospital or clinic, it’ll just be a matter of setting up drips. There’ll be a few private clinics, maybe, where you might find infusion drivers.

“We’re catering for them as well, because a large chunk of the health market in developing countries is private, and you can’t get away from that.”

He says the NHS volunteers who offer training on these items at Kyambogo are all at different points in their careers. *“We have about four or five retired biomedical engineers who are consistent supporters. But we have a full range of experience, actually, right through from people in their first few years in engineering to people approaching retirement. We’re happy to take any biomedical engineers who are currently working in the NHS who want to volunteer overseas.”*

The students have similarly varying levels of experience. *"It's a cross-section of people,"* explains Martin. *"We've had people who are already technicians in hospitals. But there's school leavers as well – it's the full gamut."*

"I would say the majority are probably school leavers, though, or people maybe a few years out of school who are still hungry for education and who see it as a way of going straight into a job."

And it seems that is not a misplaced hope. The charity stays in touch with graduates of the diploma course, and *"95 per cent of them are in employment within a year, and there are about 30-34 graduates each year".*

A look at the numbers also points to the impact the education has. *"We've followed [the graduates] and on average they seem to put back into operation an average of about three items of equipment a week,"* reports Martin. *"So if you multiply that, that is a huge amount of equipment that's going back into operation."*

Is it, he hopes, indicative of a sustainable approach to supporting African countries with medical devices. *"Up to now, the support from countries like the UK has been very ad hoc,"* says Martin. *"And it's basically consisted of individual hospitals maybe sending out an engineer to actually fix things.*

"But that's potentially quite counter-productive because you don't actually improve the capacity of the country to look after itself, and you make it dependent on handouts. So we're trying to get away from that model, and trying to empower these African countries to do it themselves."

He continues: *"It's all about handing over practical experience, and building the capacity of biomedical engineering training in Uganda."*

Certainly the capacity of courses at Kyambogo University has grown: this year, a bachelor's degree in mechatronics and biomedical engineering has been introduced alongside the diploma. It means the number of volunteers the Amalthea Trust is sending to Uganda has doubled – *"six per semester, because we're teaching two courses".*

"95 per cent of them are in employment within a year, and there are about 30-34 graduates each year".

And so, naturally, Martin is keen to find more people who might be interested in working with the charity. *"I'd emphasise you don't need to have done anything like this before, because we do hold volunteers' hands, certainly first time around. We have an experienced engineer, a senior clinical engineer from Wolverhampton, who picks you up from the airport and drives you around.*

"We rent an apartment in Uganda, so it's very comfortable accommodation, there's no food issues. So people who haven't been abroad, specifically to Africa, shouldn't really be worried about that. That's not an issue. And then as people volunteer more, they tend to want to do it on their own, and they get more adventurous!"

He also explains that the Trust has teaching materials – *"PowerPoints, student handouts, teaching notes"* – pre-prepared. *"We've got materials that people can use, or they can develop their own."*

In short, Martin says, *"a lot of the obstacles that potential volunteers might imagine are there in fact are either not there, or can be very easily overcome".* There's also plenty of information on the charity's website about what getting involved entails.

"There's a volunteer page and there's a video we made: a filmmaker came out and followed what a couple of volunteers were doing while they were out there. So that's quite informative. Plus there's lots and lots of photos on the website, and we've also got reports that individual volunteers have written about working in places like Uganda." Says one: *"I would strongly urge other clinical engineers who feel like a challenge, and are willing to share their skills and knowledge with other individuals, to volunteer: it's rewarding."*

And it seems the need for volunteers is only going to increase. While Martin stresses that any expansion of the charity's work is needs-driven – *"we wait to be invited, and we work through existing institutions in the countries concerned; we don't want to go into countries and say this is what we do, and where do you want us to do it and when?"* – there seems little doubt those needs are there.

"We have been working in Ethiopia for a couple of years, where we're providing a couple of very experienced engineers for a government-led training programme," he explains. *"And we've just been part of a bid for providing a lead engineer over a period of five years. We've got feelers out among colleges in Zambia and Jamaica as well, which are in the research and building process. Going ahead, I can easily see that we will be working in more countries."*

Certainly he's in little doubt that being involved in the charity's efforts – whether as a volunteer or an employee – is an enjoyable proposition. *"I don't get up in the morning dreading the fact I have to go and turn on my laptop and start working,"* he says with a chuckle.

"It's fun. I do feel it's a very worthwhile thing, because this is an area that is really in its infancy in developing countries. And it really can grow quickly if we put in injections of experience."

To learn more about the Amalthea Trust, including how you can help, visit the website at **www.amaltheatrust.org.uk**.

To donate or not to donate?

Has your organisation ever donated medical equipment to a hospital in a developing African nation? It's a generous act but, according to Martin Worster, it may not always be quite as helpful as you would hope.

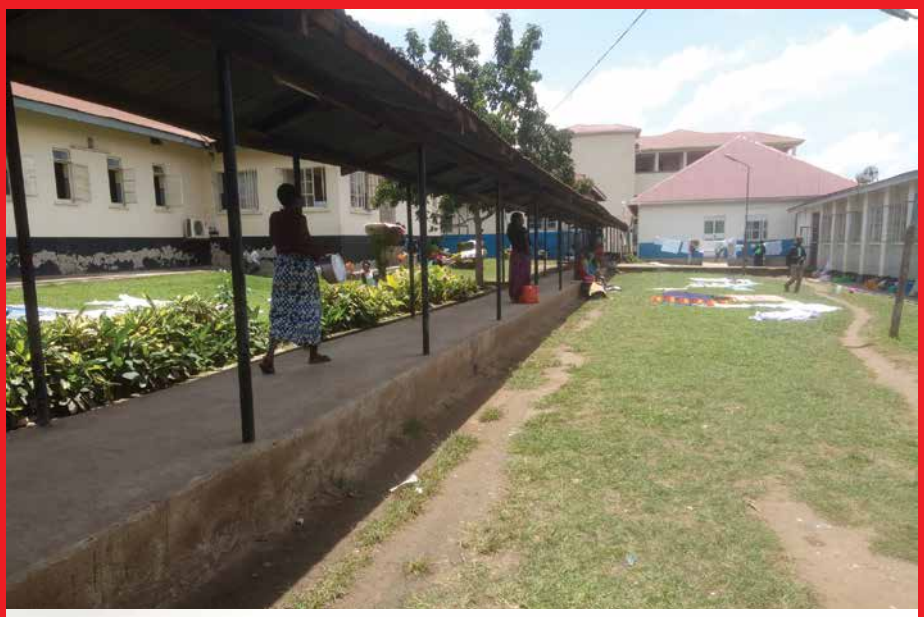
"The whole issue around donations tends to be that the donors don't ask what people want, they just ship stuff out there," he explains. *"Donors tend to decide what they've got that's available and think, well, surely they're going to need some of this so they send it out. And whenever a hospital approaches another hospital and says would you like some equipment, they are always going to say yes, whether or not it's equipment that they can actually use. They'll always say yes because they're frightened that if they say no, then they'll get no donations at all."*

He argues, then, that it's crucial to ask hospital staff in African countries what items they actually need – and in particular what models of equipment they need. *"Because a lot of donations are quite high tech and when the chips go or the motherboards break down, they're useless. Either that or the consumables that go along with the equipment are expensive and they can't afford to buy them.*

"So it's a tricky area, because donations are often driven by the donors rather than the receivers."

A better option, he suggests, could be to donate equipment to the Amalthea Trust which it can then sell to raise funds. One of the Trust's founders is Mike Hilditch, managing director of auction firm Hilditch Group Ltd. *"People can donate an item to the Trust, which Mike will then sell and give us all of the proceeds – he waives his own commission on it,"* explains Martin.

"So if a hospital has an item of equipment that they feel they'd like to donate, actually rather than giving it straight to a recipient, if you give it to us then those funds can go to train biomedical engineers."



"So if a hospital has an item of equipment that they feel they'd like to donate, actually rather than giving it straight to a donor, if you give it to us then those funds can go to train biomedical engineers."

Hi Lo blood glucose displays may confuse users

NHS Improvement

Following an incident reported to the NRLS where the display terms on a blood glucose analyser were not understood and acted upon, we shared a questionnaire with users from different care settings in order to learn more. Although there was assurance that users who completed the questionnaire understood what the terms HI and LO mean on a blood glucose analyser, we wanted to share this issue with you for awareness.

Please be mindful that some users who may not perform blood glucose monitoring frequently or who may have missed user training may be confused by such terms and therefore fail to act on them. We are confident that this is not a general concern but suggest that you may wish to review user awareness in your organisation, both with colleagues and patients who self-monitor, as an additional guarantee of good practice and understanding in this procedure.

NHS terms and conditions for procuring goods and services

The new PAQ form and associated terms and conditions documents to support procurement and purchasing 'goods and services' are now available at: **https://www.gov.uk/government/publications/nhs-standard-terms-and-conditions-of-contract-for-the-purchase-of-goods-and-supply-of-services**

The NHS terms and conditions are for the use of NHS bodies procuring goods and services from commercial organisations.

The documents provide guidance notes and associated documentation for:

- **contract version**
- **purchase order version**
- **framework agreements**
- **combined goods and services**
- **innovation partnerships**
- **dynamic purchasing systems**
- **managed services**

Although primarily focussed in England, these have been adopted in many cases by all other counties in the UK.

Updated MHRA guidance on assistive technology

Medicines & Healthcare products Regulatory Agency

The updated guidance covers the definition of assistive technology and the safe use of this type of medical device. This includes mobility aids and therapy equipment. It includes:

- **examples of assistive technology**
- **a definition of aids for daily living**
- **common safety issues**
- **sources of further information**

Available at: **https://www.gov.uk/government/publications/assistive-technology-definition-and-safe-use/assistive-technology-definition-and-safe-use#overview**