MDET

The official journal of NAMDET
Medical Device Education and Training

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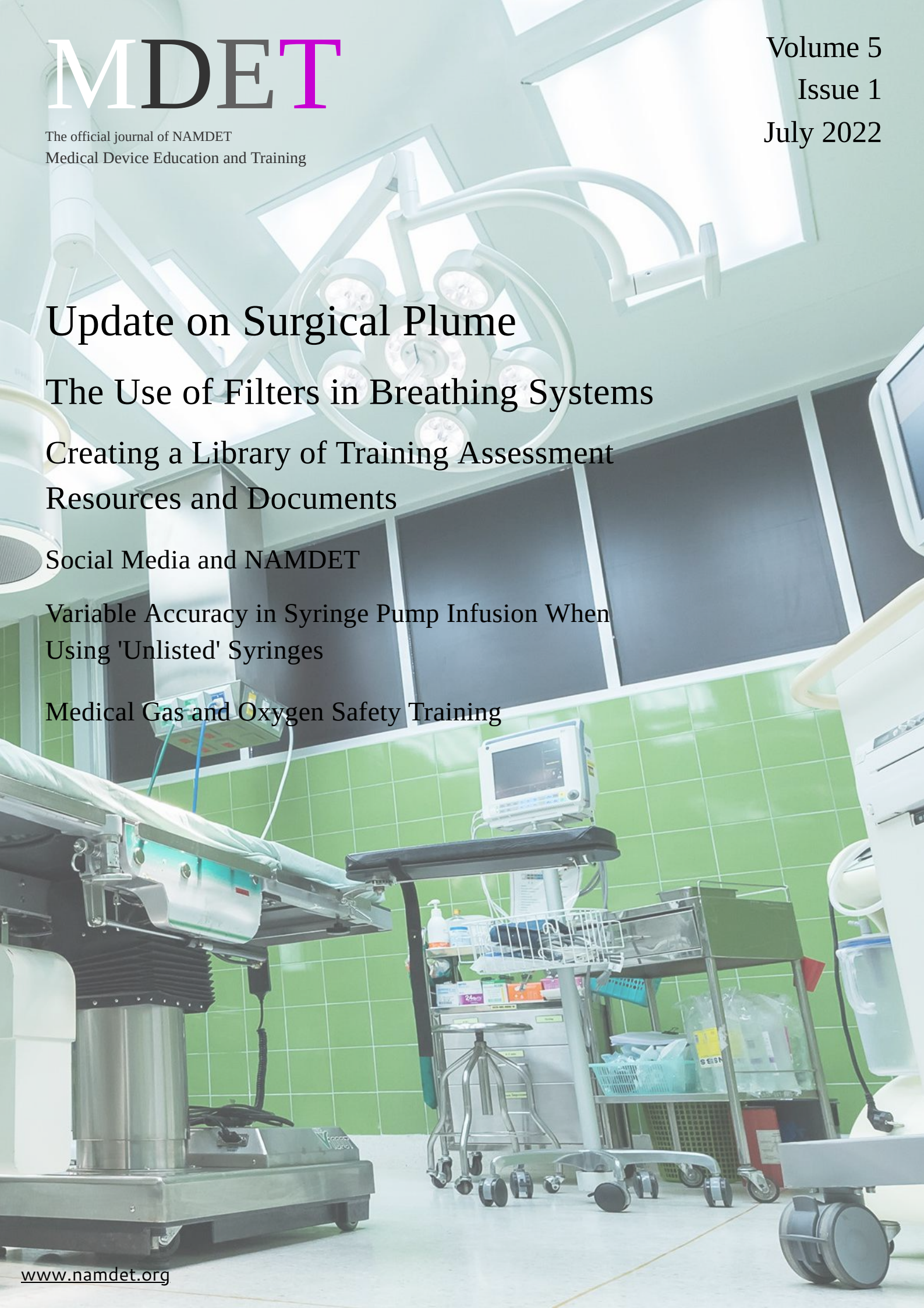

Update on Surgical Plume

The Use of Filters in Breathing Systems

Creating a Library of Training Assessment Resources and Documents

Social Media and NAMDET

Variable Accuracy in Syringe Pump Infusion When Using 'Unlisted' Syringes

Medical Gas and Oxygen Safety Training

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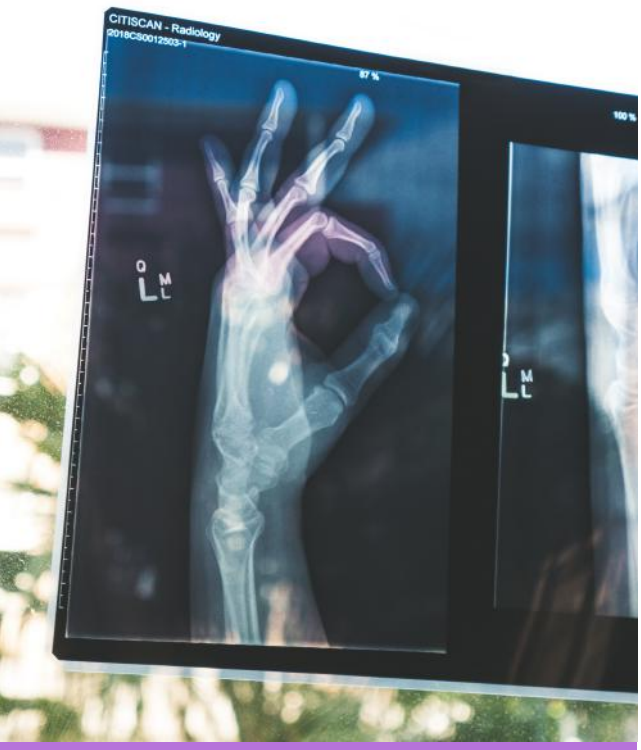

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Words from the Editor...

Despite the continued prevalence of COVID19, many feel we are now entering the 'post pandemic' era and wondering what the new world will be like for our NAMDET members, colleagues, and all our patients. Millions of treatments have been delayed, but innovation, better networking, working more imaginatively, and fresh ways of working are being developed daily. Sharing best practices and things that worked (and those that didn't) should help harmonise healthcare and point the direction of travel for the next decade at least.

Will it ever be the same again? Home working, multiple, daily TEAMS meetings, shared folders, national portals and online conferences were the norm. Without these things, then, we would never have achieved so much. NAMDET members across the UK worked tirelessly in all areas, from nightingale hospitals, running online webinars to off-site training facilities, raising our profile, winning awards and medals for outstanding contributions to healthcare, and this momentum takes us forward today.

In this edition of MDET, you'll find valuable updates on surgical plumes, HME filters, syringe pump accuracy when using unlisted consumables and exciting news about our new social media pages. Also, there are updates on two big NAMDET projects: a national training resource for **medical gas & oxygen safety,** plus a **national repository** for all medical device training materials and competency assessments via the NAMDET free portal.

Networking, improving links and sharing what we know are skillsets for our NAMDET members, and I hope you can share MDET far and wide. I look forward to meeting up with everyone at our face-to-face, prestigious annual conference for 2022 in York and seeing what the new 'norm' will look like going forward.

For all article, editorial enquiries, advertising opportunities : please use the *'contact us'* page of the NAMDET website. www.namdet.org

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NAMDET would like to thank BD Ltd. for their generous early commercial commitment, and ongoing support, which enabled this important journal to be first established. MDET is now self-funded and relies solely on sponsorship and advertorials to maintain its editions. Please feel free to contact us if you have a story, or development to share and wish to help maintain this amazing free journal.

UPDATE ON SURGICAL PLUME

Electro Surgery Consultant/Clinical Lecturer Steve Veck provides us with an update on the subject of surgical plume

Following a publication in our Official MDET Journal (Vol. 1, Issue 2, May 2017 & Vol. 4, Issue 1, June 2021), I thought it may be useful to update you, on further progress on this emotive subject, especially considering the recent pandemic we have all experienced. The SARS-Cov2 virus certainly raised many more questions, concerning just what is in Surgical Plume.

Surgical Plume is a known biohazard to our healthcare professionals, who are exposed to this daily, during surgical procedures.

Typically, when any surgical intervention using Electrosurgery (Diathermy), Laser, Harmonic Scalpel or any other cellular disruptive medical device, surgical plume is produced. This plume contains numerous chemicals and bacteria, some banned substances within the European Community. It also carries biological elements, for example pathogens, viruses and carcinogens. As well as numerous toxic and noxious gases.

The effects on our healthcare professionals that are exposed to surgical plume, are flu-like symptoms such as headache, cough, chest discomfort, sinus and upper airway irritation, sore throat, red tearing eyes, allergy and asthma reactions, and long-term illness such as bronchitis, hepatitis, COPD, and cancer as well as HPV, HIV and AIDS.

At present no mandatory policy exists within the United Kingdom, although some trusts have adopted

through local policies, supported by a full risk assessment. This has seen the use of surgical plume evacuation devices, in what they consider high risk surgical procedures.

From my perspective, **all** surgical procedures involving energy devices, can and do produce a surgical plume with the risks it entails. This is certainly evidenced in a publication by The Health and Safety Executive – Evidence for Exposure to Harmful Effects of Diathermy Plume (Surgical Smoke) Evidence based literature review 2012.

The Association for Perioperative Practice (AfPP) has set up along with The International Council on Surgical Plume (ICSP), a new group known as SPA (Surgical Plume Alliance) this group has various members, all with a common interest in surgical plume as well as bringing about positive change. ICSP has been instrumental in driving forward the opportunities for various countries to change policies within their hospitals. Our wish is to see surgical plume evacuation used, every day, on every patient, every time.

The aim of our group is to develop a strategy towards the encouragement of a policy process, within hospital trusts across the United Kingdom.

Ultimately, the hope is that these policies will lead to a much-needed mandatory process being initiated, as is already the case in many countries. Scandinavia and growing number of states in the US and Australia, and in Canadian Provinces

Given the horrendous pandemic we all experienced, this led to many questions being asked about the likely spread of SARS-Cov2 via surgical plume, hence the action now being taken.

SPA have produced a survey which was sent out to AfPP members, this consisted of some 25 questions regarding surgical plume. The response rate was excellent with some 955 members taking part, which also included some 27 surgeons. The objective of this survey was to find out how much healthcare practitioners knew about surgical plume and the potential hazards.

The respondents were a mixture of roles within perioperative care, some 68% were full time, the remainder were part-time or agency. Nearly 53% had been working in theatres for more than 15 years, the remainder between 2 and 15 years represented 41%.

93% said they were aware of the risks of surgical plume and 90% confirmed they had concerns about it. Interestingly, nearly half of those polled said they had not been provided any education or training on the risks associated with surgical plume. With slightly more saying they had received education.

The question was asked about how they received training. Some indicated self-eLearning, webinars, conferences and via commercial medical representatives. All of these are useful sources, however some medical companies delivering training may have a biased view towards those products, this is no way meant to undermine the offerings provided by such medical companies, as any awareness accurately provided is helpful.

Some of the answers were very interesting for example 96% indicated that if formal education and training, on the subject of surgical plume was available they would attend, via various platforms including webinars, eLearning and conferences.

Training needs to be part of an annual mandatory requirement to practice in the perioperative environment. It should also be included in the Induction Process for all employees.

As a British Standards Institute Committee Member, currently participating on the ISO working group, which is the Medical Gas – Surgical Plume Section. Our group (ISO TC121 SC6 WG7) has been tasked with looking at the current ISO 16571:2014 and to consider either amending it or re-working the whole document.

Steve Veck
Electro Surgery Consultant/Clinical Lecturer
UK Country Liaison ICSP
BSI Committee Member

THE USE OF FILTERS IN BREATHING SYSTEMS

Ben Satchell BSc (hons), DiPHE, RN (ADULT)
Senior Medical Device Specialist
Devices Safety and Surveillance

There has recently been some concern by various groups within the health care system surrounding the use of filters in breathing systems, including the different types of filters that are available on the market and what these filters can be used for. The purpose of this article is to explain the function and use of these filters. The article will also discuss the reason behind some of the recent concerns and actions that have resulted from these, as well as the importance of user training and familiarity with devices before using them in a clinical setting.

This article will not focus on any particular manufacturers' colour scheme or branding and all images are for general reference.

Overview of Breathing System Filters

Breathing system filters are placed into the breathing system of ventilation devices to achieve a variety of beneficial effects for the patient. The devices are generally small square or circular devices, with a connection at either end. This connection should be of a standard diameter to connect to the ventilation device itself or the tubing used in the breathing system. There are a wide range of filters on the market with varying indications and counter indications.

The manufacturers labelling system is often the most immediate way of identifying the different types of filter that can be used in the clinical area. Manufacturers typically use things such as the size, shape and colour of the filter or labelling to indicate their function, as well as the writing on the filter. Each manufacturer currently uses their own bespoke labelling system for identification.

These devices should not be confused with the dust and air filters that are placed in other areas of ventilation devices.

The decision over which type of filter to use when delivering ventilation support to a patient should ultimately be made by the clinician prescribing the therapy. A number of factors should be considered when selecting the filter, such as the needs of the patient, compatibility between the ventilation device and the filter, and the clinical setting (Al-Shaikh and Stacey 2018).

It is particularly important to consider compatibility of the filter with other devices being used as part of the ventilation system, to avoid potential complications. One of the most common complications that can arise from the incorrect use of filters is increased resistance within the system. If resistance is increased this will mean that the ventilation device will have to exert greater pressure to achieve the required therapy. This can lead to increased risk to the patient (Al-Shaikh and Stacey 2018).

Filter Types

The four most common types of filters are:

High-efficiency particulate air filter (HEPA)

These devices prevent the transmission of bacteria and viruses beyond the point it is inserted into the system. This is used to prevent cross contamination between patients when devices are transferred. These filters work using multiple layers of a meshed material that are pressed tightly together, creating a physical barrier that bacterial or viral particulates should stick to as air passes through the filter (Lorente 2012).

These filters are typically placed near the inhalation and exhalation ports of the ventilation device itself to prevent the contamination of the internal components by the patient's breath (Al-Shaikh and Stacey 2018).

Electrostatic bacterial/viral filters

These devices work in a similar way to the HEPA filter, with multiple layers of meshed material. However the meshes of these devices are electrostatically charged. The reason for this is that particulates passing through the physical barrier of the mesh will be further attracted to the positively or negatively charged strands. This is known as electrostatic filtration (Lorente 2012).

These filters are also typically placed near the inhalation and exhalation ports of the ventilation device itself to prevent the contamination of the internal components by the patient's breath (Al-Shaikh and Stacey 2018).

Heat and moisture exchange devices (HME)

These devices are used to provide heat and moisture to the gas delivered by the respiratory support device (ventilator, anaesthetic machine), to prevent the airway from drying out. This is because the air delivered by ventilation devices is typically dryer and colder than room air. Also, invasive forms of ventilation such as intubation can bypass the physiological systems that the body has for heating and moistening room air. Prolonged use of unheated, unmoistened air can have negative health effects for patients (Wilkes 2011).

These devices are typically placed at the "patient end" of the breathing system, between the breathing system and the airway adjunct, in order to function most efficiently. They typically function by trapping the heat and moisture from the patient's own exhalation in a material embedded within the filter during the exhalation phase. This heat and moisture is then returned to the patient via the air that is blown through the filter during the inhalation phase. These devices do not provide filtration for bacteria or viruses, and therefore do not prevent cross contamination of ventilation devices between patients (Al-Shaikh and Stacey 2018).

Heat and moisture exchange filters (HMEF)

These devices provide heat and moisture to the patient, and they also prevent the transmission of bacteria and viruses beyond the point they are inserted into the system.

These devices work by combining the filtration method used in the bacterial/viral filters and the heat and moisture trapping method used in the HME devices. These are usually combined as 2 separate layers within the filter. These devices do provide filtration for bacteria or viruses, and therefore can help prevent cross contamination of ventilation devices between patients (Al-Shaikh and Stacey 2018).

These devices are best introduced into the breathing system at the same point as the HME filter to function most effectively (Al-Shaikh and Stacey 2018).

Fatal Incidents Involving Breathing System Filters

In 2020 there were two unfortunate fatal incidents where the incorrect use of breathing system filters contributed to the deaths of the patients. As part of the coroner's investigation and efforts to prevent future incidents, the MHRA is working with the manufacturers of these devices to modify the labelling and instructions for use for filters to make them clearer to users.

Part of the coroner's investigation showed that there was some confusion among users surrounding the identification of different types of breathing system filters and their functions. The MHRA would like to take this opportunity to remind users that they have a duty to ensure that they are familiar with any device that they are going to use in a clinical setting. This familiarity should come from training provided by the organisation employing them. Users should also make sure they have read the manufacturer's instructions for use before employing a device in a clinical setting. Further guidance on this topic can be found in our Managing Medical Devices document. This document can be found here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_date/file/982127/Managing_medical_devices/pdf.

A review of the MHRA incident database did not reveal any similar incidents. This could be due to underreporting of the issue.

It is a commonly held misconception that incidents considered 'user error' should not be reported to the MHRA. This is not the case, as multiple reports of "use error" with a device or device type could indicate a signal that, despite the manufacturer's best efforts, the device is not user friendly when placed into practice. In these circumstances the MHRA would work with the manufacturer to determine the root cause of the issue. This root cause can then be addressed either as an iterative design improvement or a field safety corrective action by the manufacturer, depending on circumstance.

User reports are important to ensure the MHRA can identify potential issues with medical devices as soon as possible and take the necessary action. If users experience adverse incidents or concerns with a medical device they are strongly encouraged to report this via our yellow card reporting system https://yellowcard.mhra.gov.uk/.

Conclusion

There are a number of different breathing system filters available on the market and each have their own particular use profile. Users should familiarise themselves through training and manufacturers documentation on how to identify and use each type of filter employed in their clinical area. Users are encouraged to report all adverse incidents or concerns involving the use of medical devices to the MHRA so that appropriate actions can be taken to improve patient safety where necessary.

Full details of the coroner's investigation and the MHRA response can be found here https://www.judiciary.uk/publications/kishorkumar-patel-and-kofi-aning/.

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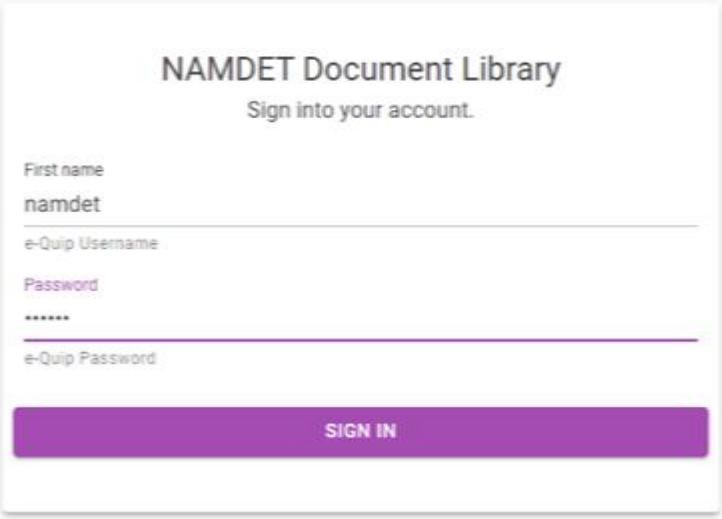
CREATING A LIBRARY OF TRAINING ASSESSMENT RESOURCES & DOCUMENTS

A look into what is coming over the NAMDET horizon with the North-West team.

Definition of a library: *'A library is a collection of materials, books or media that are easily accessible for use or borrowing by the public or the members of an institution.'*

The North-West team intends to create a library of training and assessment resources in the form of documents, videos, and user instructions, accessed through the NAMDET website for use by all of our members.

Creating an accessible library has been a complex and long-term project, commenced by Northwest NAMDET colleagues in 2018 and presented at Conference in 2020. It lost impetus after the Conference because the team could not find the right platform to store and access resources.



As the Covid restrictions lifted, most NAMDET regions started considering what projects to prioritise. This led us to collaborate at Chairs and Secretaries meetings with the London and Southeast region on this project. We now believe there is enough traction and enthusiasm to create such a library.

Such a project continues to neatly lend itself to the NAMDET principles of collaboration between our regions, NHS, and corporate colleagues.

We hope to develop a resource that can assist trainers in delivering quality training and assessments for staff who have identified a training need, thereby intending to reduce patient harm with medical devices.

As a trainer, you are likely to be an enthusiastic teacher and keen to share your expertise. Sharing your materials is one way to achieve this, a simple step that can bring many benefits:

- For you, it provides a record and recognition of the training that you have developed.

- For other trainers, it can provide an easily accessible and precious resource that can confidently be used in terms of the content covered and method of delivery.

- It should reduce the need for each trainer to create their own materials.

- For trainees, it provides a navigable resource in which to find relevant training assets and help to identify personal training needs.

Yet finding suitable materials online can be challenging, they are often widely scattered across the internet or hidden in local organisations, with no systematic way to find them.

This project has the following objectives: -

Aim: -
Plan to share training materials online, using a standardised template.

Intention: -
All NAMDET members can open the link and search for relevant models to gain access and download various training resources, documents, and other online assets. Then to be able to update and make appropriate changes to material for future use by others.

Process: -
The start is to create a template to standardise the assessment process within the training documents so anyone can easily add learning outcomes.

We must identify the factors regional members consider essential to an excellent quality training document.

Trusts and Corporate members will have different versions of these documents, so we want to create a template that employs a valid and easy-to-use assessment process.

This template will be made available in the library so anyone can develop a training document for a device and submit it back to the library for inclusion.

Using a standardised and structured approach to articulate prerequisites, learning outcomes, methodologies and assessments from both NHS and Corporate colleagues helps inform trainees about the skills they should possess before a training event.

And what they can expect to be able to do upon successful completion of their training.

Once an initial batch of documents related to medical devices considered to be widely used throughout the NHS has been developed, we would be at the start point to trial and further develop the library.

This is a reusable process that could work similarly to Wikipedia, an online resource that can be edited by anybody, anytime. The pages are made by lots of people writing together. The idea is that by using lots of different people's expertise, you can make a far more extensive resource or library and keep it up to date more easily.

> *"The intention is to make training material contribution welcoming, easy and friendly."*

The skillset of the subject matter experts of all NAMDET members is exceptional, and this is a standing invitation that if you (re)use training materials in the library, you may wish to provide feedback on the content, e.g., by reporting errors, adding learning outcomes, trainer notes or methodologies.

The users/members identify these changes to documents; therefore, they do not always have to be created before inclusion by a small editorial team. Amended or new documents can be submitted to an 'in-box' on the website, ready to be stored for checking, before being allowed to be accessible from the library.

All documents will be made available as read-only and in a format that enables changes to be made and all documents can be version controlled.

Access: -
Accessibility refers to retrieving content, which may be unrestricted or limited via an access-request mechanism. Our current view is that if we limit access to log in by NADMET members only, then quality control, responsibility and security of these documents can be better managed.

Management: -
An Editorial Group, which has yet to be established, will monitor any submissions, and check the quality of any new material. Once satisfied, it can be made available on the site.

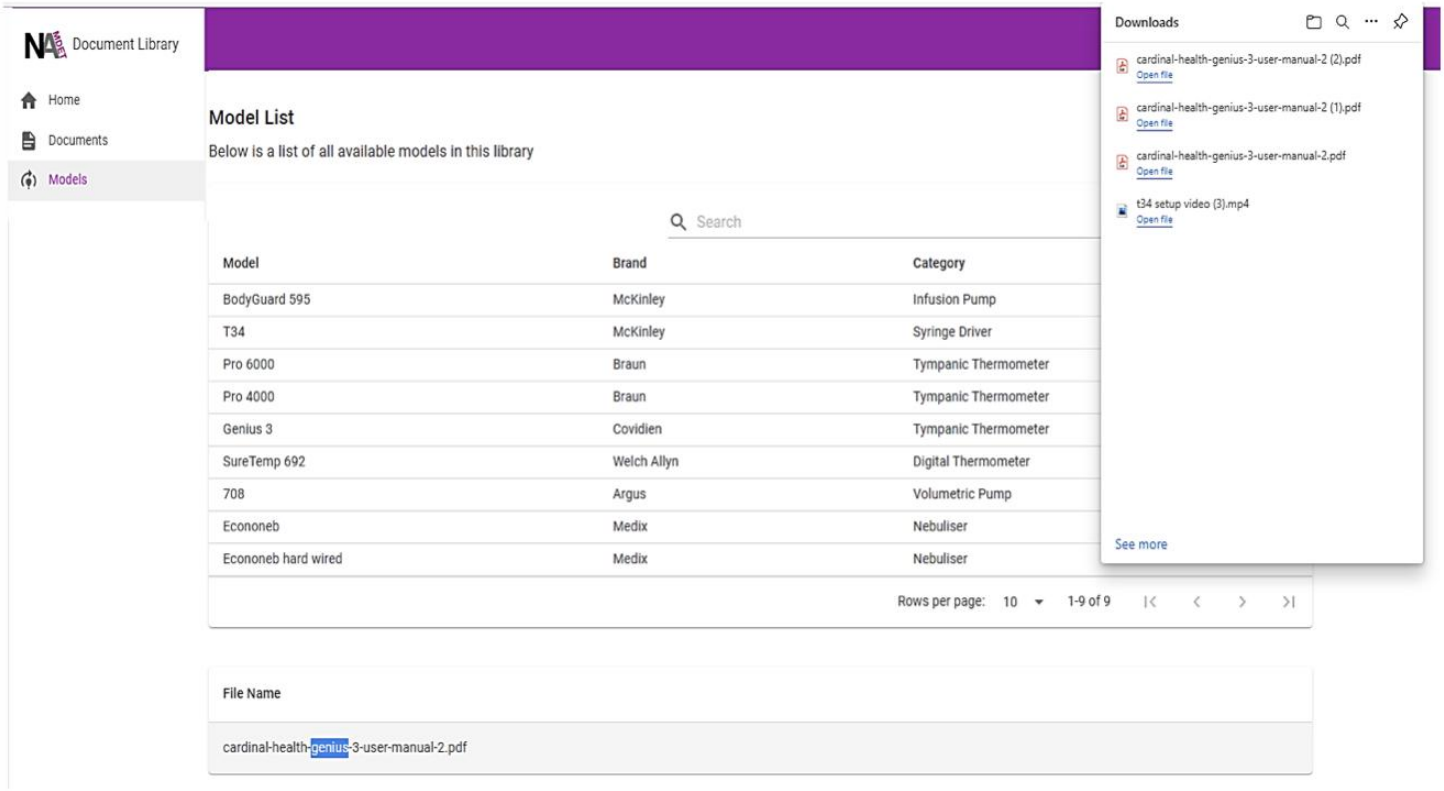
A statement must be created about using content at your own risk.

Licence: -
Where you may wish to (re)use someone else's materials in whole or just in part, then NAMDET will hopefully enter into close collaboration with Integra. And hopefully, a consideration of this relationship regarding the use of training materials can be made easier for others to (re)use and adapt by applying an appropriate license.

We must agree that the license we use can be applied to give authors and users appropriate rights of (re)use. Choosing a license is essential. Training materials and can be copyrighted in restrictive ways, so only the original authors and contributors can use, modify, or distribute them.

There will be an annual cost paid for by NAMDET.

The site: -
This project has already involved several companies in identifying a suitable developer. It has been a challenging part of the process, and they have previously been dismissed due to high enabling costs, not fit for purpose, extended time scales or issues with intellectual property.



The NW project group contacted Integra, who develop the eQuip asset register database in November 2021.

They quickly understood our specification, and after meetings in January 2022, they presented this proof of concept in March 2022.

They will be able to create a link from the NAMDET website and use 'cloud' storage for these documents and videos.

It will look and feel like a dedicated NADMET library but with close collaboration with Integra.

The documents page can search the site, or there is a search option on the model's page. You can select the file you need, simply download it to open and save it.

Above is a snapshot of the model page.

The exciting part now is to develop this platform. We need to be aware of what is achievable from a developer's perspective, but what do you think is essential functionality and what may be desirable?

We have already asked for thumbnail photographs in a dedicated column for ease of device identification and adding a statement about using content at your own risk, but this is also a request for ideas from NAMDET members to develop the site.

What do you think?

Would you like to be involved?

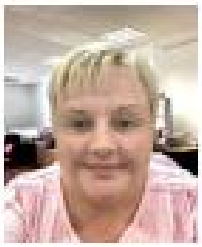
Any feedback please to the NADMET North-West Team.

We hope to present at the November 2022 NAMDET Conference in York and update everyone about this project.

Patient Safety and Experience Bulletin

The Dudley Group NHS Foundation Trust

Issue 165, 27th April 2022



Each edition of the Patient Safety and Experience Bulletin is guest edited by a subject matter expert. In this edition we look at **medical devices training** with guest editor **Lisa Wood**, core medical devices trainer.

MEDICAL DEVICES

Almost every patient that enters the doors of our Trust, will at some point be attached to or have a medical device in situ, from the smallest patients in NNU receiving inotropes via the Alaris CC pump to the elderly and sick patients connected to the McKinley T34 receiving end of life treatment. Whatever the circumstance your patients find themselves in, it is our legal duty to provide safe care.

Core medical devices are a group of high volume/quality devices used within the Trust. I am the new core medical devices trainer for The Dudley Group, my background is neonatal nursing and paediatric ED. Just three weeks in to the role, I was made aware of a serious incident where recently, a patient came to harm from a medical device within the Trust.

TRAINING TO BLAME...

The root cause was the initial training provided by the device representative. Risks had not been brought to the attention of staff despite the company having knowledge of the risk that cause the patient harm.

Staff could vaguely recall the training that had received, four years ago. It was very basic and not to the standard it should have been.

WHAT STANDARD OF TRAINING ARE WE TO EXPECT AS A MINIMUM FROM COMPANY REPS/TRAINERS?

MHRA has a whole section on training which address the initial training from external reps. Also, The Life Sciences Industry National Credentialing Register sets national standards for healthcare professionals working in the life sciences industry, providing reassurance to the NHS.

These questions should be considered each and every time an external rep is invited to deliver device training:
Are staff aware of what should be included in the content of initial training in a device from a medical representative?
Are staff in receipt of training of the representative's role?
In what capacity are they in attendance e.g. sales?
What is the main agenda of the rep when they are training?
Are they singing from the same hymn book when it comes to the expectation of staff to have robust and accurate training that looks at the device in use from every perspective that governs the delivery of self care?
Are they qualified to deliver this training? What are their credentials?
What should the training contain?

Any user of a device needs to understand how the manufacture intends the device/equipment to be used, and how it normally operates to be able to use it effectively and safely. (MHRA 2020)

• Representative delivered training SHOULD include:
• A discussion of differences between models, compatibility with other products and any contradictions or limitations on use.
• Use of accessories and how they may increase or limit the use of the device.
• Use of controls.
• Use of displays, indicators, alarms etc.
• Discuss requirements for maintenance and decontamination, including cleaning, in line with the manufacturer's instructions and relevant local procedures.
• Demonstrate use to show end users how to use the deivce.
• Explore troubleshooting, including potential issues such as those identified in safety advice from the MHRA, manufacturers and other relevant bodies.
• Discuss recognising device defects or when a device is not working properly and know what to do.
• Discuss the importance of reporting device-related adverse incidents to the MHRA and be familiar with the organisation's reporting procedure.
• Share identified risks with recipients of training.

CHAMPION OR KEY TRAINERS

Many reps are now limited to just two attendances a year to support, so I am looking at becoming a 'Train the Trainer' for many of the devices.

I also want to recruit more champion trainers or 'key trainers' from clinical areas who can continue to deliver training and assessing of staff using devices within their departments. Becoming a champion trainer is a fantastic opportunity for staff to personally and professionally develop their coaching, mentoring and assessing skills. This role will give your revalidation a super boost too!

Please get in touch if you are interested in becoming a key trainer for a core device, and visit the revamped Medical Devices Hub page for training dates and device information, e-learning and other modes of learning.

SOCIAL MEDIA AND NAMDET

It's good to stay in touch, and in 2022 there's many ways of doing that. From text message, Whatsapp, email, voicemail, LinkedIn, Instagram, Facebook, Twitter, TikTok, Snapchat, Facetime, Messenger, phone call, video call, Teams and Zoom. The list goes on and on!

We found ourselves using many of the above in our personal lives more and more as restrictions prevented us from continuing out 'normal' lives through 2020 and 2021. Who would have thought we would have become so familiar with the phrase *"you're on mute!"* and *"Am I sharing"*, as technology steps up to help us continue to be effective trainers and educators. Many of us have become virtual trainers delivering training sessions using Teams or Zoom, although at times this has been challenging. I for one had never expected to be developing the skills a Youtuber has. Technology has certainly enabled us to continue to communicate with each other when face-to-face has not been possible.

Over recent years NAMDET has steadily embraced social media and all that entails. You may or may not have noticed the NAMDET media teams have gradually increased the groups' presence on social media platforms.

> *"YOU'RE ON MUTE!!!"*

Understanding how these platforms are used and will be used is important. Networking is probably its primary use. Staying in touch between regional NAMDET meetings, sharing information with colleagues at the click of a button, and promotion of NAMDET at a national or even international level.

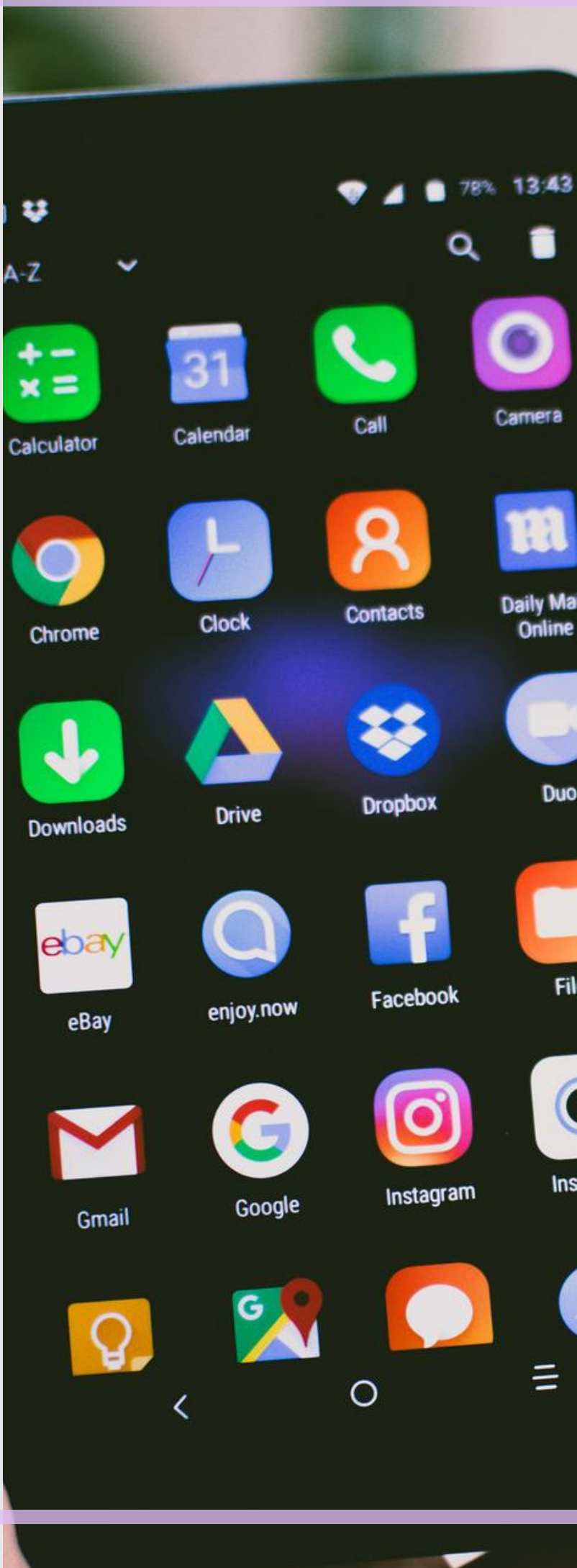
Seeing social media as a notice board of activity, pointing members to regional groups and national events where the detail is held, is the best way of looking at it. Professional use of the above platforms will act as an effective tool, helping NAMDET to grow and develop as it works towards achieving its five objectives.

So contribute, share, get involved and stay connected...See you online!

NAMDET's social media profile has continued to build. Here is where you can find us:

- NAMDET National Page
- Midlands Group
- London and SE Group
- North West Group

- namdet_insta
- @namdet_
- Search 'NAMDET'
- Search 'NAMDET'



e-Learning for Healthcare was formed in April 2007 to deliver a range of programmes, after a successful pilot with the Radiology-Integrated Training Initiative (R-ITI) which generated a model for the future delivery of generic and professional healthcare training. In 2013, e-LfH transitioned across to Health Education England and continues to work in partnership to develop e-learning programmes to support the health and care workforce.

e-LfH is now in the process of delivering or developing more than 450 e-learning programmes in collaboration with organisations including Royal Colleges, Department of Health and Social Care, NHS England and NHS Improvement and Public Health England.

NAMDET is pleased to help lead on the e-LfH 'Medical Devices' training and e-learning modules and looks forward to the development and delivery of new courses throughout 2022 and 2023.

The numbers

77 million +
elearning sessions launched on the Hub

2 million +
registered users

31 thousand +
elearning sessions available within 450+ programmes

IV Therapy Passport

Laser Safety

Medical Equipment


Management and Leadership Skills


Human Factors / Ergonomics (Safety Science) for Patient Safety: Level 1 – Understanding

Just some of the hundred of free modules

https://www.e-lfh.org.uk/

NHS
Health Education England

VARIABLE ACCURACY IN SYRINGE PUMP INFUSION WHEN USING 'UNLISTED' SYRINGES

Sarah Jennings, Patient Safety Clinical Lead (Medical Devices)
NHS England and NHS Improvement

We recently reviewed a reported serious incident where a patient had a cardiac arrest following surgery. The syringe pump infusion had been commenced using a syringe which wasn't listed in the drop-down pump profile. Whilst the pump performed as expected, the low-rate infusion ran at a slightly faster rate than expected, likely as a result of the different dimensions of the unlisted syringe. This was discovered when trying to deliver a bolus of the medication however the infusion was near its end, with insufficient volume to bolus.

Syringe pumps are unable to accurately determine exactly which manufacturers syringe is loaded, due to the fact there are several brands of syringe that are similar and, in some cases, identical in size. Although syringe pumps can be configured to accept several manufacturer brands of syringe, the user is required to confirm the correct syringe at the start of the infusion.

There may be an assumption by users that fluids and medications continuously infuse at the programmed rate, however it can vary by +/-5%. Training materials from pump manufacturers highlight many variables that can affect infusion accuracy, including the need to select and confirm use of a syringe type listed in the pump menu.

Therefore, a full assessment of the patient, the medication and the infusion pump set up, including the closed system consumables, should be taken into consideration by healthcare professionals; all of which is generally included within education and training for infusion devices.

Although there were several additional and combined factors that were potentially involved in the incident we reviewed, we thought it worth sharing with NAMDET members as a useful example to relate to when providing infusion pump education and training.

The Systems Engineering for Patient Safety (SEIPS) framework (Holden et al, 2013; Carayon et al, 2006), as seen in the visual below, enables a human factors review to understanding work systems. The interactions demonstrate how selecting the wrong syringe, where other variables are also present, can combine to influence outcome (please note the following list is not exhaustive):

- the critically ill nature of the patient
- the busy setting of the ITU department where there are multiple alarms and noises
- the potential for staff interruption and distraction
- the likelihood there will be multiple infusions for the patient
- the environment or patient space which may prevent positioning of multiple infusion pumps in close proximity to the patient or at an appropriate height
- the types of additional consumables within the infusions system
- the medication (in the reported incident, this was Noradrenaline, which infuses at a low rate and has a short therapeutic half-life)

Where there are many variables in healthcare, it can be challenging to avoid some degree of influence on infusion accuracy. However, accessing and selecting a syringe type that conforms with the pump can be

supported by controls in the system, which would positively enable a more accurate and reliable infusion.

Therefore, in addition to pump training and education there may be possibilities for system considerations too.

Some regions have standardised syringe syringe brands used across all their organisations, and with the development of Integrated Care Systems (ICS) where patients may increasingly move from tertiary to secondary care, this may be a useful consideration. This may also capture specific pathways of care where patients regularly transfer between an acute provider and specialist units. Aligned procurement of syringes to one brand across a region or locality where patients can move or are frequently transferred would be a system wide change supporting safety in terms of education and training too. Concerns around supply disruption and manufacturer support would also need to be explored to ensure system and product reliability.

Alternatively, there may be local considerations to review syringe types used in organisations where pumps are often transferred due to patient movement and perhaps to include more syringe types in the pump menu to support pump use in locations where syringes may be different. This may however enable mis-selection from the drop-down menu. So it is understanding what system provides optimum control in specific settings, which may be a balance until pumps themselves can support safer use through accurate syringe recognition.

Procurement of new pumps should preferably include Wi-Fi enablement to support the ability to remotely add/remove syringe types from the menu if there are local supply disruptions affecting syringe brands necessitating change. Systems to communicate any such changes between procurement, materials management teams and medical device management teams should ideally also be tested, to assess the impact and reliability of the system.

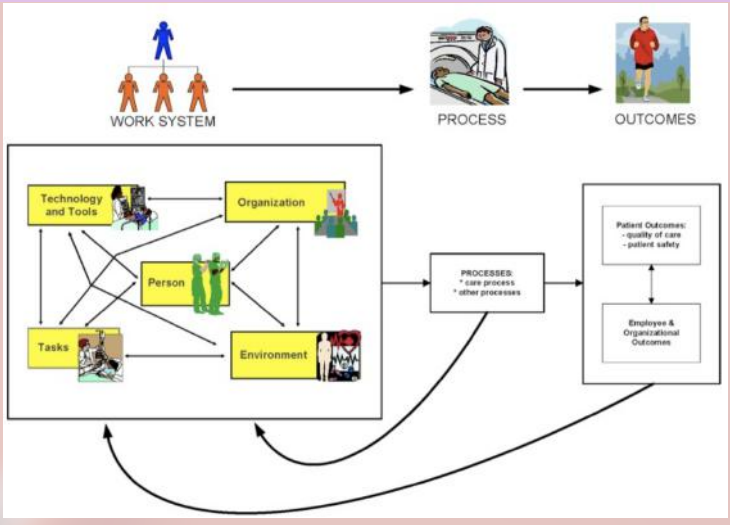


Image reproduced from Human Factors and ergonomics as a Patient safety practice ©Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety

Some large organisations may provide equipment maintenance and servicing for external providers in addition to their own assets. Where similar model pumps for multiple different organisations are being maintained by one EBME/service area there may be occasions where error can occur in applying the wrong organisation asset label for example. Discussion and consideration of processes to segregate devices may reduce occurrence. In addition, review of on device labelling and consideration for additional labelling may support staff in identifying appropriate devices at point of care.

However, despite all these examples of measures to facilitate appropriate syringe selection, until there are significant technical advances, the responsibility to select and confirm the right syringe, remains with the user.

Advances in infusion pump technology and device recognition could eliminate this step in the future and provide improved accuracy and assurance in infusion expectation. Additionally, extending barcode scanning of the device and consumable linked to the patient and the user (also linked to their training record) could be valuable system improvements. In the meantime, we are very grateful for the role that NAMDET members provide in promoting medical device education and training, both to support the user in doing the right thing and improving patient safety.

LEARNING TO NAMDET CONNECT 2022

Annual Conference

Thursday 17th November

2022

York Racecourse Conference Centre

Knavesmire Rd, York, YO23 1EX

National Association of Medical Device Educators and Trainers

Don't forget to register

This year's conference theme is **Learning to Connect**, focusing on how NAMDET is best placed to help drive forward medical device training, assessment and competencies regarding connectivity within healthcare. Speakers from the NHS, regulatory bodies, industry, and medical equipment companies will share their insights and how learning to connect with medical devices takes centre stage. NAMDET members will also be sharing their projects.

Our 3-course evening network dinner on Wednesday 16th November is being held at the Marriott Hotel, near the racecourse (Special rate applies). There are plenty of other hotels along Tadcaster Road to accommodate all sorts of budgets. Please book your own hotel direct.

There is easy access and plenty of on-site parking at the spacious York Racecourse Conference Centre (YO23 1EX). Also great access (taxi or bus) from the main York railway station.

LEARNING TO NAMDET CONNECT 2022

Book early to avoid disappointment, visit the NAMDET website for more information and to book your place. www.namdet.org

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National Association of Medical Device Educators and Trainers

Exhibitor Information

NAMDET's highlight event of the year is being held in the historic city of York, at York Racecourse Conference Centre. Numbers attending have grown year-on-year and 2022 promises to be the biggest event we've held to date. There are spaces for 150 delegates and 25 key exhibitors, with a mixture of Premium and Standard stands available. **This year we have kept the fees at 2019 prices.**

Premium Stand (10ft space) £1500
Standard Stand (6ft space) £950
(all stands include 2 delegates)

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LEARNING TO NAMDET CONNECT 2022

To book your place, and for all exhibitor and conference details, contact Andy Flood, Conference Co-Ordinator: andy.flood@namdet.org

MEDICAL GAS AND OXYGEN SAFETY TRAINING

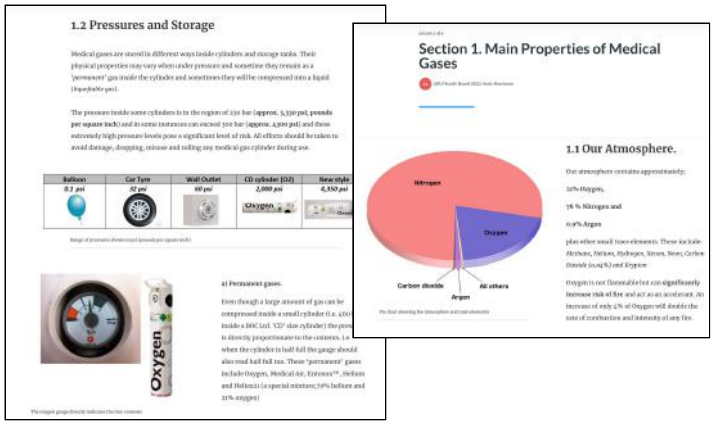
Our Medical Gas NAMDET project team has been busily working away on a new national e-learning course for the safe use of medical gases and oxygen safety. The final DRAFT version is undergoing review as we speak, and is hoped to be launched in the next few months. This national 'free to access' programme will be available via the e-Learning for Health (eLfH) website and available 24-7.

The course has a number of key modules including basic introduction to gases, safe transport, clinical use as well as modules on pressure regulators, safety and a final assessment and certificate on completion.

The course also includes a free 'Workbook' that can be downloaded as a useful reminder and useful resource for future reference. This brand new e-learning course has been designed using the 'Articulate' e-learning software and fits into the ESR and eLfH training portal. The course includes a number of easy to follow modules. This interactive training will guide you through the safety features, important things to know about medical gases and also cover regulators, cylinder use and safety notices.

Alongside this new course, a new **step-by-step** instructional training course has been designed for porters that change high pressure manifold cylinders and this can be accessed as a useful resource too.

Final tweaks are being made to the content and we hope to have good news to share in the next few weeks and launch the training for all staff to use for free going forward.



CONFERENCES AND WEBINARS OF INTEREST

Access the NAMDET **website here**; to see all registration details or click on the links to find out more.

Please checkout the NAMDET website as new posts, and events are added regularly. Sign up for free NAMDET membership and get email posts and automatic notification when each new post is added.

MEDICAL DEVICE NEWS

The UK is to strengthen regulation of medical devices to protect patients

New plans to strengthen the regulation of medical devices to improve patient safety and encourage innovation have been published. The UK is seizing the opportunities provided by leaving the EU to bring forward new legislation that goes further to improve people's health. To signify products have met these world-leading standards will carry the UKCA marking. Following the UK's exit from the European Union (EU) the Medicines and Healthcare products Regulatory Agency (MHRA) has a unique opportunity to improve how medical devices and in vitro diagnostic medical devices (IVDs) are regulated in the UK. The package of reforms will apply to medical devices such as hearing aids, x-ray machines and insulin pumps; new technologies such as smartphone apps and Artificial Intelligence (AI); as well as certain cosmetic products like dermal fillers. **For the full story access this link.**

Philips' effort to repair or replace millions of recalled sleep apnea and ventilator machines is being hampered by supply chain constraints, with the company unable to know far in advance when components, particularly computer chips, will be available. The logistical issues are limiting the number of replacement devices and repair kits the company can produce and ship for the over 5.5 million machines that have been recalled, leaving patients with no idea when replacement machines will arrive. "*We are working hard to overcome serious challenges to device production and delivery, not in the least caused by component and freight capacity shortages in the world,*" CEO Frans van Houten said in a video statement. "*And while we cannot provide exact delivery dates, we are committed to completing over 90% of the production and shipments to our customers in 2022.*"

Two new innovative devices get clearance in the USA

Apple Watch monitoring features for AFib, Parkinson's cleared by FDA in the USA. Apple received 510(k) clearance for a new feature for its smart watch that shows users an estimate of how frequently their heart rhythm shows signs of atrial fibrillation (AFib).

A smartwatch-like blood-monitoring device made by LiveMetric that's cuff-free was granted 510(k) clearance by the Food and Drug Administration. LiveMetric secured the clearance after showing its LiveOne device is substantially equivalent to Tensys Medical's TL300, a continuous blood-pressure monitor used at the bedside in healthcare facilities.

Healthcare Safety Investigations Conference 2022

HSIB
HEALTHCARE SAFETY INVESTIGATION BRANCH

Agenda

Our exciting agenda includes:

- a focus on our maternity, national and investigation education programmes
- sharing our learning so you can help make patient care safer in your organisation
- updates and expertise on conducting professional healthcare safety investigations in your setting
- the future of our national and maternity programmes, as they form into either the Health Services Safety Investigations Body (HSSIB) or the new maternity Special Health Authority.

By registering, you'll receive updates about the conference in the run up to the event, including opportunities to sign-up to breakout sessions.

Register for your free place

Thank you to all our NAMDET members and supporters for their contributions towards this edition of MDET

National Association of Medical Device Educators and Trainers

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