MDET

The official journal of NAMDET
Medical Device Education and Training

Volume 3
Issue 1
May 2020

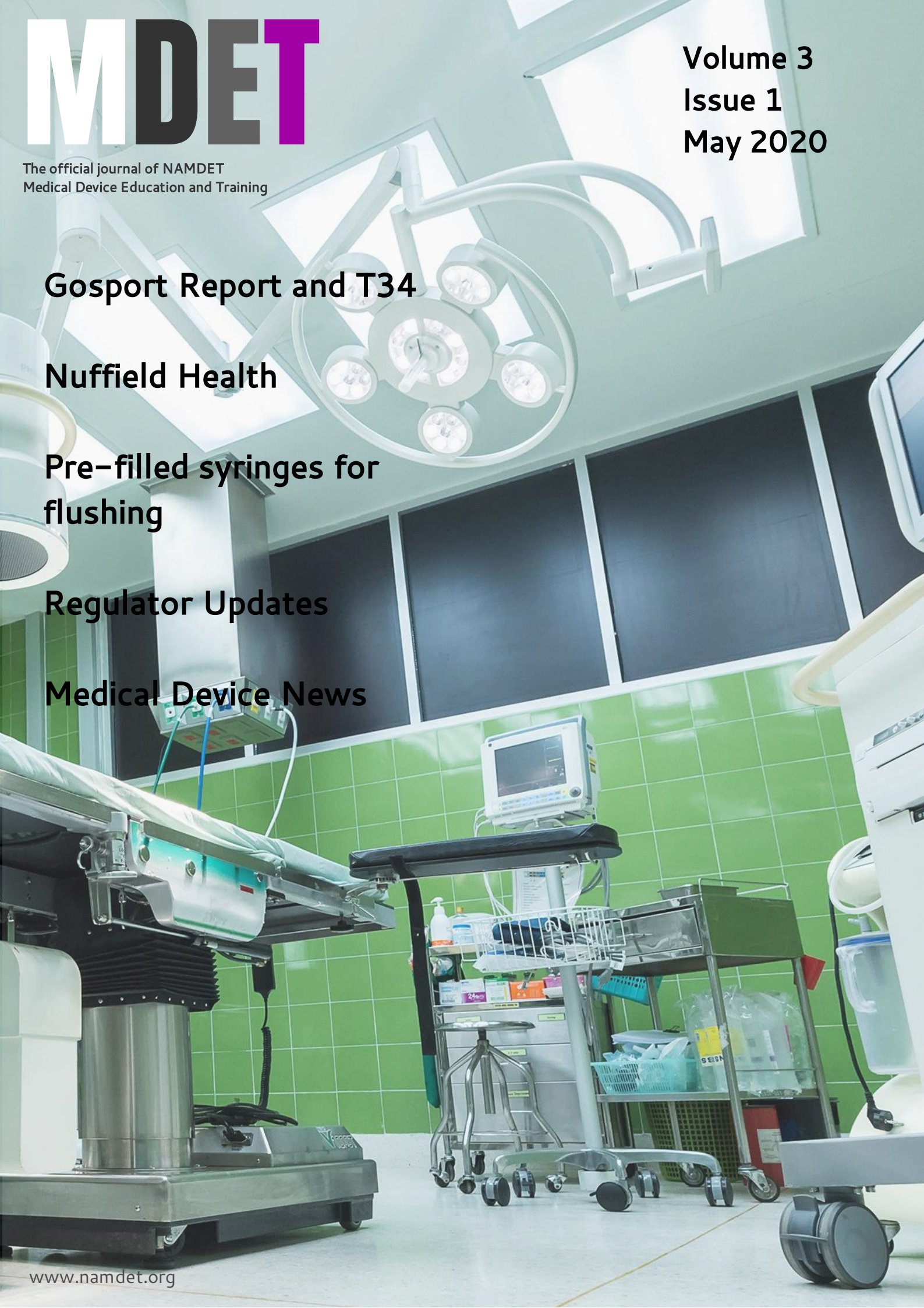
Gosport Report and T34

Nuffield Health

Pre-filled syringes for flushing

Regulator Updates

Medical Device News



www.namdet.org

MDET

The official journal of NAMDET
MDET: Medical Device Education and Training

Welcome to the newest edition of MDET, the free journal for all medical device educators and trainers. This new style journal is available as an electronic 'flipbook' and also a downloadable PDF copy for those looking to save and keep their own MDET library going forward.

We cannot thank our previous publisher enough: Mike Dixon (Specialist Publishers Ltd.) for giving us the helping hand and getting NAMDET started with MDET and their support for our annual conferences.

MDET journal was also started with support and funding from BD Ltd. and they continue to support the project throughout 2020. We welcome additional support and articles from all our sponsors, key contributors and supporters to make this journal a continued success.

The new style MDET has updates and stories from members, some seasoned writers and of course people writing up articles for the first time. Our small journal team is on hand to help support and get these into print and we need input from across the UK, regional meeting updates, stories of interest and any new innovative devices and ideas around device training.

We also have opportunities to share new device launches, product portfolios and industry issues as well as member's achievements.

Please feel free to use the 'contact us' page via the NAMDET website **www.namdet.org**

Message from NAMDET:

It's been a long time since we last updated you with MDET, so a big apology from the MDET team and apologies also to those that kindly submitted articles and stories and the delay in getting your first stories to print.

Changing journal teams in 2019, changing to a new style journal and of course pressures of work have meant that things got delayed. Conference 2019 was a huge success and also a massive workload for the team too. As soon as we settled down to look forward to 2020 the world wide pandemic has hit, and hit the NHS and our industry partners very hard.

We very much hope that you, your family and your colleagues are keeping safe and I know that our members are doing all they can to help teach, train and support their hospitals and project teams in this monumental effort.

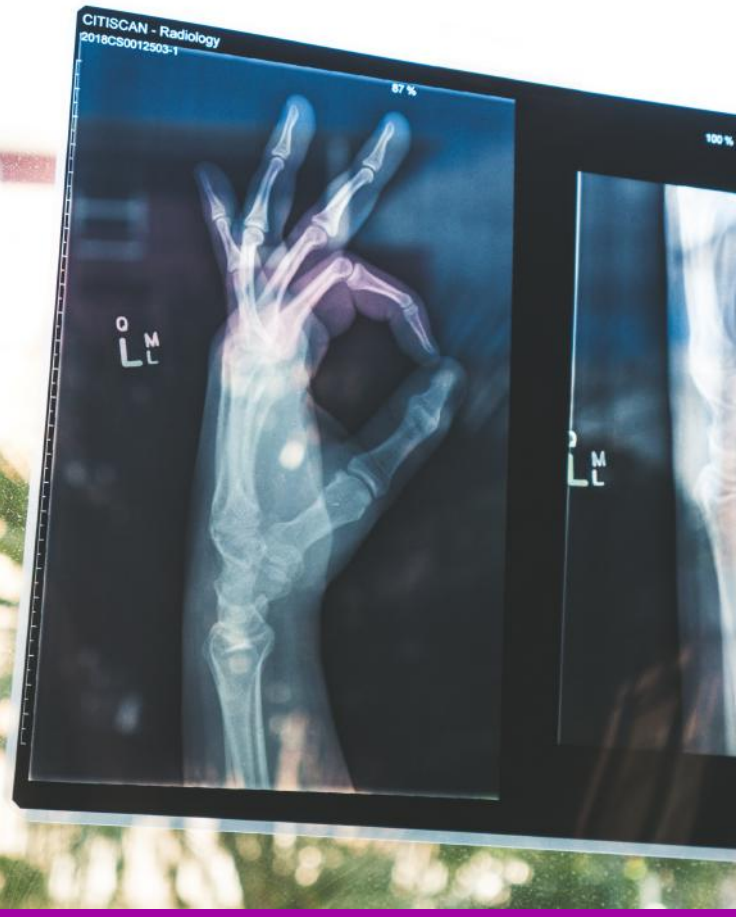
NAMDET has linked in with HEE (Health Education England and eLfH (E-learning for Health), shared training links and resources, and suppliers are doing all they can to raise the status and standing of medical device trainers and providing a forum for mutual support.

Thank you.

Our profession has never been so affected, and we are all finding new ways of working, sharing and supporting each other and we cannot do this without the great support of our friends and colleagues from the NHS, Industry, private sector through to industry and academia partners too.

Going forward, the world will now be a very different place, our NAMDET family is strong and we have come together to support each other in these unprecedented times. We hope you keep safe, keep loved ones safe and continue to support each other throughout 2020 and beyond.

Paul Lee, Chairman NAMDET



NEW JOURNAL FORMAT FOR 2020

Welcome to the new e-format for MDET in 2020. Our journal team have been busy gathering up stories of interest that we think will be a great addition to previous editions.

NAMDET is only able to produce and share this great resource with input from our members and industry partners so please keep the stories and items of interest coming. There is no charge for having your story, or item added to the journal so please feel free to use the 'contact us' page on the NAMDET webiste: www.namdet.org

Our latest edition includes articles and stories about medication, devices and training competencies as well as updates from regulators and colleagues working in medical device training roles.

Contents:

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

Paul T. Lee
Chairman NAMDET, MDET Editor

Jordan Lee:
Managing Editor MDET

NAMDET would like to thank BD Ltd. for their generous early commercial commitment, and ongoing support, which enabled this important journal to be established, and also maintained for 2020.

THE GOSPORT REPORT AND THE T34 SYRINGE DRIVER – A CLINICAL PERSPECTIVE

Dr Andrew Dickman BSc MSc DPharm FFRPS
MRPharmS Consultant Pharmacist – Palliative Care
Academic Palliative and End of Life Care Centre
Royal Liverpool and Broadgreen University Hospitals NHS Trust
andrew.dickman@nhs.net

Palliative Care and the Syringe Driver/Pump
Palliative care is a discipline where patients often exhibit co-morbidity. Consequently, complex symptom management regimens are frequently employed. Although a holistic approach to patient care is adopted, with the development of individualised treatment plans that incorporate pharmacological, psychosocial and spiritual approaches, medication certainly represents a vital part of palliative care.

Symptoms tend to increase during the last days and weeks of life and pharmacological interventions are essential for adequate alleviation(1). Common symptoms experienced by patients at the end of life include: pain, respiratory tract secretions, agitation, delirium, restlessness, dyspnoea, nausea and vomiting(1-4).

Administration via the oral route should be maintained for as long as practical, although a given patient's condition may deteriorate such that it is no longer possible to administer medications this way. When the oral route is inappropriate, for example due to vomiting, decreased level of consciousness or swallowing difficulties, an alternative method of administration must be adopted. One option that has been embraced by palliative care services in the UK is administration via a continuous subcutaneous infusion (CSCI). A CSCI is an alternative method of administering medications which can be used to maintain symptom control in a patient no longer able to tolerate oral medication.

A syringe pump (also referred to as a syringe driver) is used to deliver a CSCI. Such portable battery- operated devices were first used in 1978 by Dr Martin Wright to deliver desferrioxamine for the treatment of thalassaemia in children(5). Shortly after this Russel described the application of CSCI in the context of palliative care for the small number of people in whom the oral route had proved too difficult(6).

He commented that 'it' (*the syringe driver*) is simple to use, effective, reliable, foolproof, and, being small and lightweight, allows complete mobility.' The administration of medications by CSCI was subsequently adopted by palliative care services in the UK, eventually becoming fundamental for continued symptom management(7,8).

In 1994 and 1995 concerns were raised about confusion between the two Graseby devices...

To this day CSCI delivered by syringe pumps have benefitted many thousands of patients experiencing what would otherwise be unrelenting pain and other distressing symptoms in the last hours and days of their lives.

A survey in 1992(9) showed that the two most commonly used syringe drivers in several hospices within the UK were the Smiths Medical (formerly Graseby) devices: the MS16A (Fig.1 blue front panel: rate set at mm/hour) and the MS26 (Fig. 2 green front panel: rate set at mm per 24 hours). The predecessor organisation to MHRA (the Medical Devices Agency) published two hazard notices on the Graseby syringe drivers in 1994 and 1995. These notices drew attention to the potential for confusion between the two types of syringe drivers which could result in inappropriate infusion rates leading to over-infusion and there had been patient deaths as a result. Further concerns were raised in 2001 and 2003. The notices advised users to refer to the labels developed by the manufacturer that were colour coded, clearly stating in bold on the control panel whether they were millimetres per 1 hour or per 24 hours. In October 2007, Australia introduced a registration process for medical devices overseen by its Therapeutic Goods Administration (TGA). This meant all companies had to submit documentation to prove their products met appropriate standards. The company manufacturing the Graseby syringe drivers (Smiths Medical) did not believe the drivers met those required standards and so withdrew them from the Australian market. Similar measures were put in place in New Zealand.

The T34 syringe driver replaced the Graseby MS16A (Blue) and MS26 (Green) devices.....

In December 2010, the National Patient Safety Agency (NPSA) in the UK issued a Rapid Response Report about ambulatory syringe drivers. Between 2005 and 2010 the NPSA received reports about 8 deaths and 167 non-fatal incidents involving older ambulatory syringe drivers with rate settings based on length of liquid, rather than volume. The NPSA required that all organisations in the NHS and independent sector who used ambulatory syringe drivers develop a purchasing for safety initiative by December 2011. Older devices had to be replaced within a five-year period and such devices have now been removed from the UK market.

Fig 1. Graseby MS16A, an hourly rate device set in mm per hour

Fig. 2 Graseby MS26, a 24 hourly rate device set in mm per 24hrs (day)

Fig. 3. T34 syringe pump, set in ml/hr, with additional alarms including: syringe removed, low battery, nearly empty and occlusion alarm.

..the NPSA made recommendations to help address the issues...

The NPSA recommended that suitable ambulatory pumps should address the following criteria:(10)

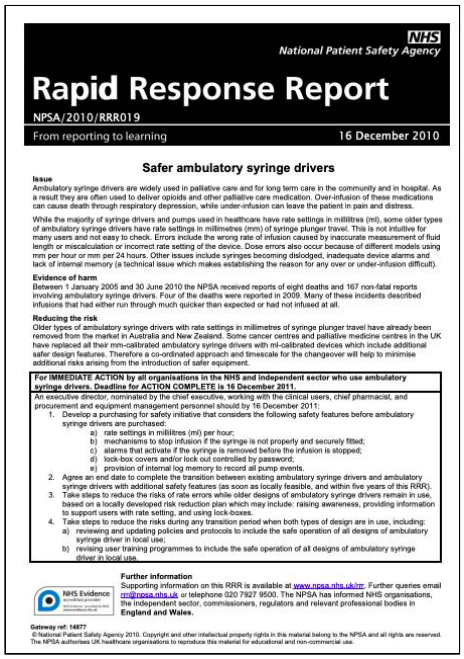
- **Rate settings in millilitres (mL) per hour**
- **Mechanisms to stop infusion if the syringe is not properly and securely fitted**
- **Alarms that activate if the syringe is removed before the infusion is stopped**
- **Lock-box covers and/or lock out controlled by password**
- **Provision of internal log memory to record all pump events**

There are also International Standards, issued by the IEC (International Electrotechnical Commission) to which infusion devices should attain. One such standard that is pertinent to syringe drivers is IEC 60601-2-24, which includes particular requirements for the safety of infusion pumps and controllers, e.g. alarms that alert the user to situations such as power interruption, line occlusion, syringe displacement or tampering. Most UK palliative care services switched to the T34 syringe pump [Fig-3] differs from the older syringe drivers in that the delivery rate is based on volume, rather than length. It is more sophisticated than the older devices and inherently safer. Importantly, it complies with IEC 60601-2-24 and addresses all of the recommendations proposed by the NPSA.

Gosport Report

In 1988, and again in 1991, nurses at Gosport War Memorial Hospital expressed concerns over the use of diamorphine and Graseby syringe drivers. It was reported that diamorphine was being used indiscriminately, via syringe driver, for patients with no obvious signs of pain. Additionally, it was alleged that the staff responsible for setting up and administering syringe drivers had not been trained properly. It has taken 30 years for the nurses to be vindicated. In June 2018, the Gosport Independent Panel, headed by James Jones, former Bishop of Liverpool, published the inquiry into opioid-related excess mortality at Gosport War Memorial Hospital. The misuse of diamorphine and syringe drivers, which often followed the clinical instruction '*please make comfortable*' was shown to have shortened the lives of at least 456 patients. At least another 200 patients had similarly had their lives shortened, but no records existed for them. (11).

The appointment of Dr. Jane Barton a local GP who was appointed clinical assistant at Gosport coincided uncannily with the rise in the use of opioids and deaths. The Crown Prosecution Service decided not to charge anyone after three previous investigations by Hampshire Constabulary into 92 deaths. But Kent Police, after reviewing the evidence found by the Gosport Independent Panel opened a new criminal investigation into the deaths in April that year.



NHS
National Patient Safety Agency

Rapid Response Report

NPSA/2010/RRR019

From reporting to learning — 16 December 2010

Safer ambulatory syringe drivers

Issue

Ambulatory syringe drivers are widely used in palliative care and for long term care in the community and in hospital. As a result they are often used to deliver opioids and other palliative care medication. Over-infusion of these medications can cause death through respiratory depression, while under-infusion can leave the patient in pain and distress.

While the majority of syringe drivers and pumps used in healthcare have rate settings in millilitres (ml), some older types of ambulatory syringe drivers have rate settings in millimetres (mm) of syringe plunger travel. This is not intuitive for many users and not easy to check. Errors include the wrong rate of infusion caused by inaccurate measurement of fluid length or miscalculation or incorrect rate setting of the device. Dose errors also occur because of different models using mm per hour or mm per 24 hours. Other issues include syringes becoming dislodged, inadequate device alarms and lack of internal memory (a technical issue which makes establishing the reason for any over or under-infusion difficult).

Evidence of harm

Between 1 January 2005 and 30 June 2010 the NPSA received reports of eight deaths and 167 non-fatal reports involving ambulatory syringe drivers. Four of the deaths were reported in 2009. Many of these incidents described infusions that had either run through much quicker than expected or had not infused at all.

Reducing the risk

Older types of ambulatory syringe drivers with rate settings in millimetres of syringe plunger travel have already been removed from the market in Australia and New Zealand. Some cancer centres and palliative medicine centres in the UK have replaced all their mm-calibrated ambulatory syringe drivers with ml-calibrated devices which include additional safer design features. Therefore a co-ordinated approach and timescale for the changeover will help to minimise additional risks arising from the introduction of safer equipment.

For IMMEDIATE ACTION by all organisations in the NHS and independent sector who use ambulatory syringe drivers. Deadline for ACTION COMPLETE is 16 December 2011.

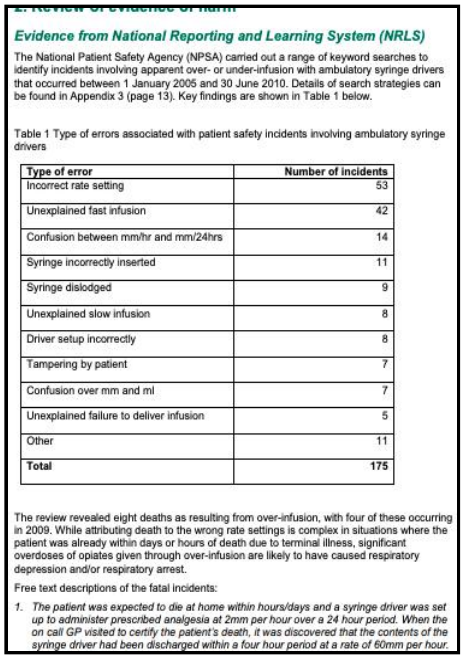
An executive director, nominated by the chief executive, working with the clinical users, chief pharmacist, and procurement and equipment management personnel should by 16 December 2011:

1. Develop a purchasing for safety initiative that considers the following safety features before ambulatory syringe drivers are purchased:
   a) rate settings in millilitres (ml) per hour;
   b) mechanisms to stop infusion if the syringe is not properly and securely fitted;
   c) alarms that activate if the syringe is removed before the infusion is stopped;
   d) lock-box covers and/or lock out controlled by password;
   e) provision of internal log memory to record all pump events.
2. Agree an end date to complete the transition between existing ambulatory syringe drivers and ambulatory syringe drivers with additional safety features (as soon as locally feasible, and within five years of this RRR).
3. Take steps to reduce the risks of rate errors while older designs of ambulatory syringe drivers remain in use, based on a locally developed risk reduction plan which may include: raising awareness, providing information to support users with rate setting, and using lock-boxes.
4. Take steps to reduce the risks during any transition period when both types of design are in use, including:
   a) reviewing and updating policies and protocols to include the safe operation of all designs of ambulatory syringe driver in local use;
   b) revising user training programmes to include the safe operation of all designs of ambulatory syringe driver in local use.

Further information

Supporting information on this RRR is available at www.npsa.nhs.uk/rrr. Further queries email rrr@npsa.nhs.uk or telephone 020 7927 9500. The NPSA has informed NHS organisations, the independent sector, commissioners, regulators and relevant professional bodies in **England and Wales.**

Gateway ref: 14877



Evidence from National Reporting and Learning System (NRLS)

The National Patient Safety Agency (NPSA) carried out a range of keyword searches to identify incidents involving apparent over- or under-infusion with ambulatory syringe drivers that occurred between 1 January 2005 and 30 June 2010. Details of search strategies can be found in Appendix 3 (page 13). Key findings are shown in Table 1 below.

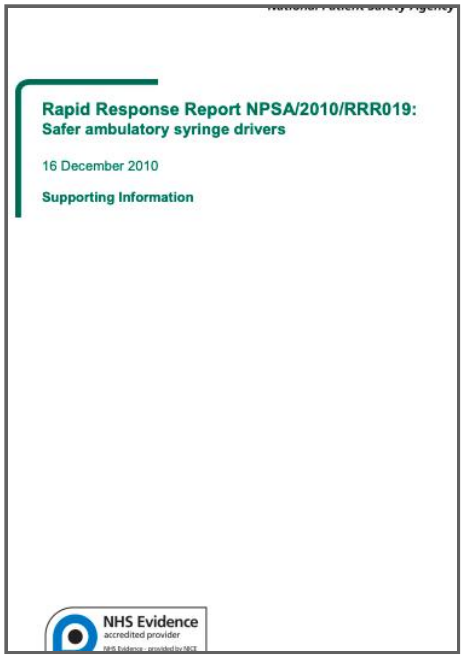
Table 1 Type of errors associated with patient safety incidents involving ambulatory syringe drivers

Type of error	Number of incidents
Incorrect rate setting	53
Unexplained fast infusion	42
Confusion between mm/hr and mm/24hrs	14
Syringe incorrectly inserted	11
Syringe dislodged	9
Unexplained slow infusion	8
Driver setup incorrectly	8
Tampering by patient	7
Confusion over mm and ml	7
Unexplained failure to deliver infusion	5
Other	11
Total	**175**

The review revealed eight deaths as resulting from over-infusion, with four of these occurring in 2009. While attributing death to the wrong rate settings is complex in situations where the patient was already within days or hours of death due to terminal illness, significant overdoses of opiates given through over-infusion are likely to have caused respiratory depression and/or respiratory arrest.

Free text descriptions of the fatal incidents:

1. *The patient was expected to die at home within hours/days and a syringe driver was set up to administer prescribed analgesia at 2mm per hour over a 24 hour period. When the on call GP visited to certify the patient's death, it was discovered that the contents of the syringe driver had been discharged within a four hour period at a rate of 60mm per hour.*



Rapid Response Report NPSA/2010/RRR019: Safer ambulatory syringe drivers

16 December 2010

Supporting Information

NHS Evidence
accredited provider

...the Gosport Independent Panel review.....

Following the publication of the report of the Gosport Independent Panel, there were a number of media reports citing Graseby syringe drivers as a major contributor to deaths in NHS hospitals. Most, if not all, reports were spurious and wholly inaccurate. Some examples are shown below:

· Gosport inquiry panel accused of "NHS cover up" over faulty syringe drivers The Telegraph, 23 June 2018
· NHS use of 'unsafe' syringes to be examined BBC News 24 June 2018
· Gosport Hospital scandal syringes may have caused deaths of thousands of NHS patients The Mirror, 24 June 2018
· The great NHS cover - up: opiate syringes may have killed thousands The Sunday Times, 24 June 2018
· Faulty opiate injection pumps used in Gosport scandal to be reviewed amid fears over deaths across NHS The Independent, 25 June 2018

It is important to stress that the Gosport Report is not critical of syringe drivers. Bishop James Jones stated in a letter to the Sunday Times after the report of the Panel was published that 'The four clinicians [on the panel] and the whole panel were unanimous that syringe drivers were not responsible for the over-prescription that led to the shortening of 456 lives'. Nonetheless, irresponsible and inaccurate journalism caused unnecessary and significant distress for patients and relatives. As a result of the Gosport Report, and the ensuing media frenzy, changes have been made to clinical practice procedures (locally, at least) with respect to the use of CSCIs and the T34 syringe driver.

A CSI must not be commenced without a documented conversation to explain the rationale with the patient and the family/carer. This forms a record demonstrating full awareness of the indication for use and and will also provide them with an opportunity to ask questions and address any concerns. The patient may lack mental capacity to make a decision about the CSI, or their mental capacity may be in question.

A decision therefore may need to be made for the patient in their best interests. Additionally, due to the negative connotations disseminated by the media, the term "syringe driver or pump" is no longer used in discussions with the patient and the family/carer, while the alternative "continuous subcutaneous infusion" is advocated. The occurrences at Gosport War Memorial Hospital resulted from catastrophic professional and institutional failings; insinuations that faulty syringe drivers were to blame was wholly inaccurate.

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9. David J. A survey of the use of syringe drivers in Marie Curie Centres. Eur J Cancer Care 1992; 1:23-28.

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IMPROVING CUSTOMER SAFETY THROUGH THE NURSE-LED DEVELOPMENT OF A MEDICAL DEVICE MANAGEMENT WEBSITE

Claire Johnson MSc, BSc (Hons), RGN – Governance Lead Medicines Management and Medical Devices. Nuffield Health.

Nuffield Health delivers wide-ranging health and wellbeing services to approximately 1.4million people each year. In order to deliver these services over 27,000 medical devices are required to assess, monitor and treat our customers across the UK. These all need to be appropriately maintained and be safely used by competent practitioners. The development of a web based toolkit for the staff of Nuffield Health has supported sites in acute and non-acute environments to have easy access to documents and compliance tools to ensure both staff and equipment are managed well to ensure customer safety.

Nuffield Health are the leading not-for-profit independent healthcare organisation, providing a wide range of health services through our network of hospitals, medical clinics, fitness and wellbeing centres and diagnostic units across the UK. Within our 31 hospitals alone, we have approximately 1,345 acute beds – the size of a NHS trust spread over a large geographical area.

This alone raises a challenge; now consider the wide variety and acuity of medical devices required to carry out the breadth of wellbeing and healthcare expertise we provide across 322 acute and non-acute sites. These medical devices need to be maintained and repaired and importantly, be used safely by staff who have been assessed as competent to safely use them.

Standardisation – what standardisation?

Within our sites, we have a wide variety and acuity of medical devices that need to be maintained, repaired and we need competent staff to safely use them.

There are at least **27,000** assets recorded on our database
6,000 different makes and models of medical device
128 different device models to take blood pressure

Projects are currently underway to standardise emergency equipment and infusion pumps across hospital sites, but we have a long way to go.....

As a nurse with a passion for patient safety...

As a nurse with a passion for patient safety, I set myself the challenge to develop an innovative way to develop a number of readily accessible toolkits providing documents for managers and staff across the business to be easily used to support medical device and user governance and thereby ensuring customer safety through standardised document and processes.

I believe that medical device management and therefore customer safety works more efficiently across a large organisation if the managers and device users have the tools and support to ensure safe practices. These tools are not only documents and processes but also forums for networking and sharing of lessons learnt and best practice.

My initial aim was to provide a network platform through which the managers at acute sites could have open communication and support from their peers, ensuring customer focus. Due to the nature of the business, each site has its own successes and challenges around ensuring customer safety regarding medical devices which needs to be continually addressed and explored. These are wide ranging and include the acquisition of devices, cultural practices of clinicians and management of patient safety alerts, to name a few. It became evident that across the organisation, both acute and non-acute sites were seeking guidance and support in how to manage a number of medical device management issues.

My preliminary aim soon evolved into developing a web based communication platform to support all sites; providing a library of medical device competency documents, customer safety processes, compliance dashboards and audit tools to ensure safe governance procedures were adopted.

Utilising the business-wide extranet facility and through the patient support of our IT team, I developed a web page approach, creating a site where all Nuffield Health staff can access a toolkit of information to drive customer safety through safe medical device management and use. The site provides easy access to support safety alert management, together with medical device maintenance information and documents to support use and competence assessment of medical devices.

This alone raises a challenge; now consider the wide variety of acuity of wellbeing and healthcare expertise we provide across 322 acute and non-acute sites. These medical devices need to be maintained and repaired and importantly, be used safely by staff who have been assessed as competent to safely use them.

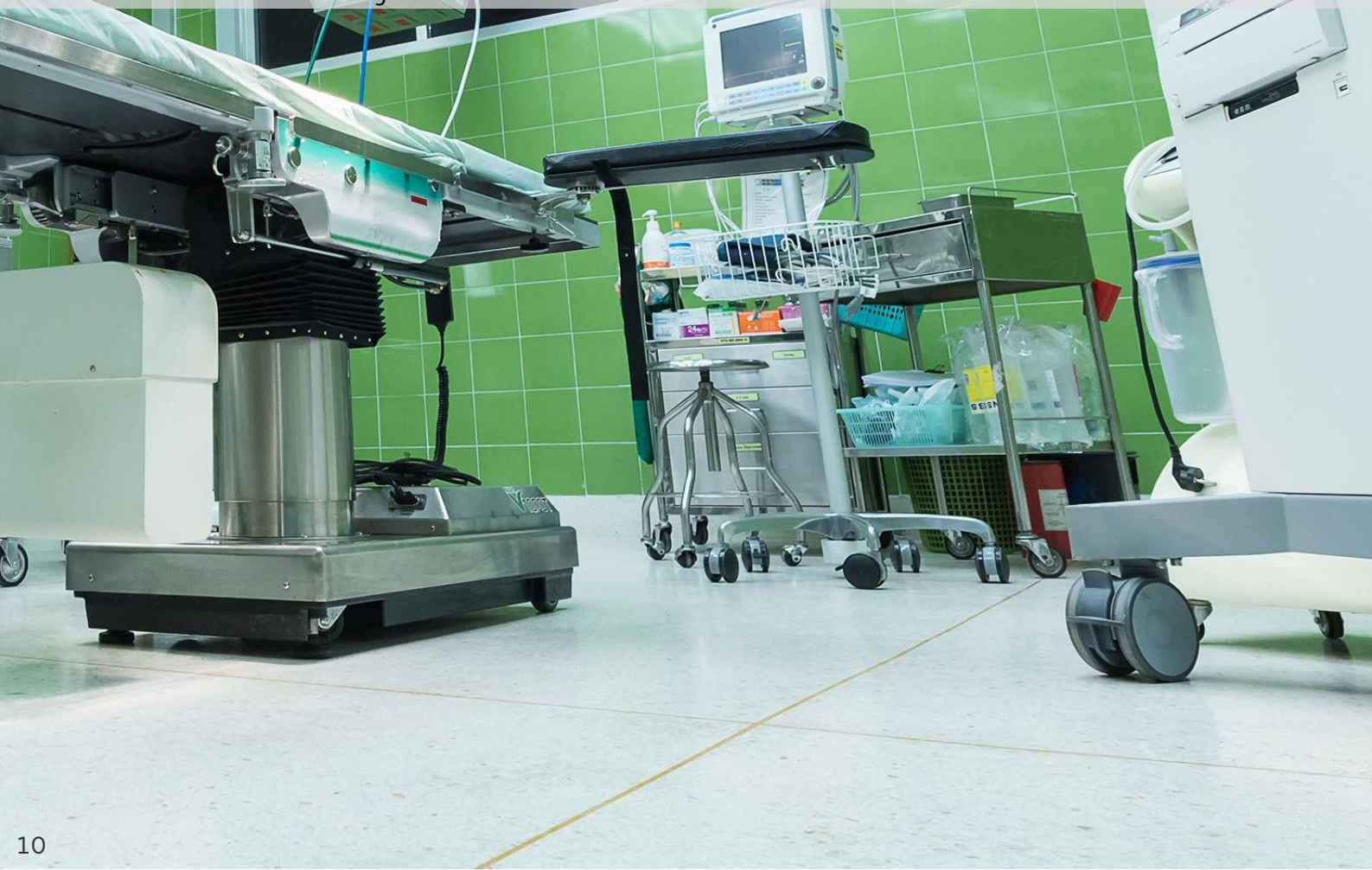
The development of the documents...

The development of the documents has been supported by a network of Medical Devices Leads (MDLs) in place across the acute sites. MDLs range from Matrons to Health Care Assistants and cross a number of professions, bringing together a wealth of knowledge and experience. The MDL role is taken on in addition to the MDLs employment responsibilities and time enabled for the role greatly differs. Consequently some MDLs felt they did not have the time to effectively manage the medical devices at their site and required initiatives to support this. I was aware of these site differences and also recognised the risk of becoming autocratic and potentially causing further dis-engagement.

Having undertaken post graduate education programmes in change management, I understood it was important to understand the challenges the MDLs were experiencing and empower this vital workforce in order to obtain engagement with any change I was hoping to implement. The MDLs had never met each other so to encourage networking and engagement, a day of workshops for the MDLs to attend was arranged.

During these workshops, the MDLs collaborated to review the tools (e.g. audit documents, competency assessment tools and maintenance management processes) they felt were needed to support medical device management compliance. These were developed and piloted before being subsequently loaded onto the extranet site for all sites to access and utilise to improve customer safety through increased governance processes.

The greatest achievement within this project is the work being undertaken regarding clinical competency assessment and compliance, a challenge frequently raised across healthcare providers. Due to the large number and wide variety of medical devices across Nuffield Health, medical device training is provided by the device manufacturer and cascade trainers are trained to support their site. A generic competency document was in use, however this could be used to assess the competency of the user of both a thermometer and an anaesthetic machine.



Through the extranet page....

Through the extranet page, medical device users are now (where available) able to obtain and download the competency document specific to the device they are using and therefore providing a more robust assessment tool. This is being achieved by developing relationships with manufacturers to support on-site training and obtaining electronic copies of their device specific assessment documents, which are uploaded in to a library on the extranet site.

A recent development is also the ability for clinical competency assessment compliance to be monitored by sites utilising a recently launched competency tracker, which already is proving to be a valuable tool for sites as they are able to record when competency assessment of each device staff use is undertaken, when assessment is next due and provision of a compliance percentage which can be reported at department and hospital level.

Five key outcomes and implications of the project:

1. Development of competency assessment and recording mechanisms to support practitioners to provide safe, competent care

2. Delivery of standardised information in an easily accessible and easy for sites to use – 'no need to write their own'

3. Influencing culture and behaviour to highlight need for safe medical device compliance practices

4. The value of technology as an enabling force to overcome geographical and communication challenges

5. Raising of the 'Medical Device Safety' profile across the organisation with potential financial implications to ensure devices are fit for use.

Nuffield Health

This has been a huge undertaking, which is by no means completed and is continually evolving to meet changing needs, particularly as my involvement with the management of medical devices at the non-acute sites has increased. It is evident that their requirements differ from those in the acute areas, with medical device management education being required as staff are often from a non-clinical background. Increased recognition that devices utilised in these environments, although they may be considered not to be 'high' risk, is required to ensure it is equally important to have comprehensive maintenance records and staff that are using the medical devices are competent to do so, thereby ensuring customer assessment is undertaken safely and accurately.

Working with my colleagues in this part of the business, future plans include greater support for non-acute site managers through the extranet site and potential network development. A non-acute compliance dashboard is currently being developed and trialled to monitor site compliance with safety alert management/action and medical device maintenance schedules. A further challenge to address is the logistics of communications across the large number of consumer and corporate sites, as they are not all on the Nuffield Health IT network, which will take time and resources to overcome.

Claire Johnson MSc, BSc (Hons), RGN – Governance Lead Medicines Management and Medical Devices. Nuffield Health.

Blood transfusions with BD Alaris™ pumps

Delivering safe patient care and work-flow efficiencies

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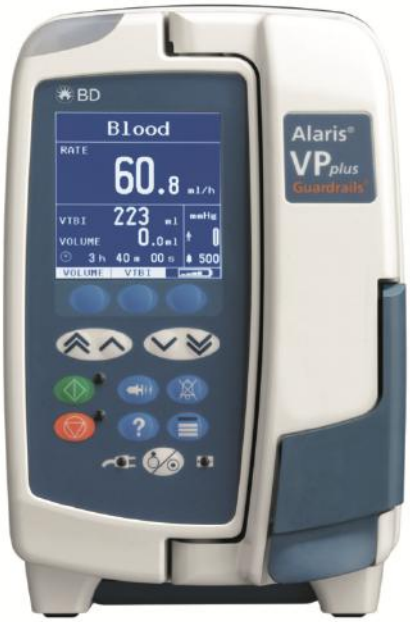
BD Alaris infusion pumps can help support your patients' blood transfusion needs and also help:



- Enhance compliance and safety[3,4]
- Decrease blood wastage and additional costs[3,5]
- Improve clinicians' efficiency[3]

To find out more visit: bd.com/uk/pumping-blood

0000CF04175 Issue 1 Date of Preparation February 2019

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BD

PRE-FILLED SYRINGE FOR FLUSHING IV CANNULA; TO BE PRESCRIBED OR NOT PRESCRIBED? – THAT IS THE QUESTION

(CE marked medical device or POM: prescription only medicine?)

Paul T. Lee, Medical Devices Training Manager, Morriston Hospital, Swansea Bay University Health Board

John Terry, Head of Pharmacy, Neath Port Talbot Hospital, Swansea Bay University Health Board

Introduction

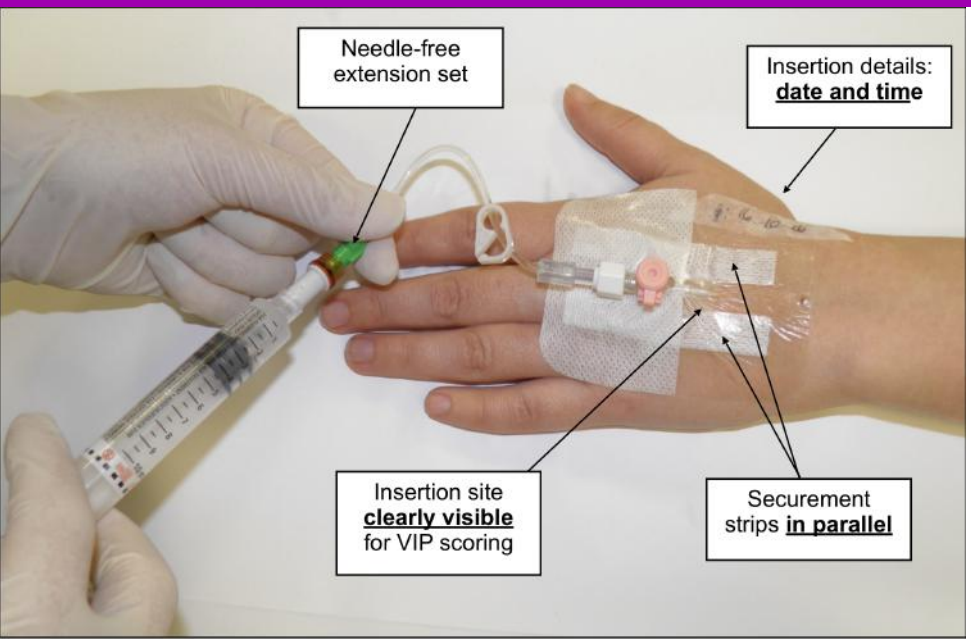
A peripheral intravenous cannula is a device that is inserted into a peripheral vein (e.g. hands and arms) for therapeutic purposes e.g. administration of medications, fluids and/or blood products. Figures vary greatly, but suggest that as many as 40% of all patients will have an intravenous cannula in situ during their treatment or stay in hospital or healthcare setting.

An integral part of their safe use and ongoing management, is that cannulae are flushed (with an appropriate solution) after insertion, after each use to help remove the risk of accidental infusion of any residual medication, and at regular intervals (e.g. every 24 hrs) to help maintain patency and reduce the chance of cannula occlusions(1).

Regardless of the type of peripheral intravenous cannula used, 4 basic principles of care for the device remain the same:

1. Minimise infection risk by always using ANTT (Aseptic Non Touch Technique)
2. Maintain a 'closed' intravenous system with minimal connections to reduce the risk of contamination
3. Maintain a patent and correctly positioned cannula
4. Prevent damage to the device and associated intravenous equipment

IV cannula should be held securely in place [to reduce the risk of dislodgement] and dressed with an appropriate IV dressing that is dated at the time of insertion.



1. Cannula securement strips in parallel (not crossed) securing the cannula wings
2. Insertion details recorded on dressing
3. Insertion site 'clearly visible' for ongoing VIP scoring
4. Needle free extension set

Note 1: A ready-to-use pre-filled syringe of 0.9% sodium chloride used to flush an IV (Intravenous) cannula.

Note 2: a 10mL diameter syringe is used to reduce the overall pressure exerted although only 5mL volume is used per flush.

Follow ANTT and SICPS....

All intravenous peripheral cannula should be inserted, accessed, maintained and removed using Aseptic Non Touch Technique (ANTT) and Standard Infection Control Precautions (SICP). Inserters should also adhere to employer's policy and current guidelines in relation to Safer Sharps Regulations and guidelines around the Control of Substances Hazardous to Health (COSHH).

All practitioners carrying out the procedure are fully accountable and responsible for safe practice in the insertion and removal and have a professional duty to maintain their knowledge and skill. It is their responsibility to ensure that they undertake this role competently and with the required clinical skills. Cannulation should be carried out upon the request of a Registered Practitioner and this could be a Medical Practitioner or a Registered Practitioner who is acting upon specific approved protocols and guidelines. Cannula should be flushed regularly, the insertion site checked for redness, swelling and signs of infection. A suitable Visual Infusion Phlebitis (VIP) score should also be recorded.

Common Fluids for Flushing

Historically, a solution of 'heparinised saline' was recommended for the effective flushing of IV cannula. However, apart from a few specific areas, use has been superseded by 0.9% sodium chloride, which is equally effective and also mitigates the residual risk of accidental use and administration errors with heparin(2).

Today, the most common fluid administered as an IV flush is sodium chloride 0.9% as it is compatible with many IV drugs and fluids. This is purchased and stocked as small plastic or glass ampoules and is classified as a Prescription Only Medicine (POM) due to the intended IV route of administration.

Legislation supported by employer's policies stipulate that all POMs for administration to patients must be prescribed by an appropriate, authorised practitioner.

Alternative arrangements include using a Patient Specific Direction (PSD) or a Patient Group Direction (PGD), the latter, while commonly employed for flushing arrangements has legal restrictions with regard to which groups of staff can operate under the direction. A record of administration must be made and retained using authorised records (e.g. the Medicine Prescription, In-Patient Administration Chart, patient notes or other formal recognised methods of recording).

A number of health care organisations in the UK have an accepted practice for IV flushes using pre-filled syringes of 0.9% sodium chloride (licensed as a CE marked medical device) to be administered without a formal prescription or administration record. They have accepted the use of the device as part of the routine flushing of patient's cannula during insertion, for maintenance and/or pre and post IV medication requiring a 0.9% sodium chloride flush. It should be noted that where sodium chloride injection 0.9% ampoules are used as a flush **the administration must be prescribed and recorded** on the appropriate documentation

As with all invasive procedures, there are inherent risks with IV cannulation....

Governance in Swansea Bay University Health Board

In Swansea Bay University Health Board, over 300,000 Intravenous cannula are purchased each year. Intravenous infusions account for over 500,000 infusions and this includes IV bolus, gravity and via medical infusion pumps. Intravenous infusions are a high-risk procedure and patients can be exposed to risk of infection and error in each step. This process is safely managed, and risks mitigated, using a range of safe products, controlled processes and trained and competent staff. A series of products are available (see Table 1) for the safe flushing of peripheral IV cannula and for pre and post infusion of IV medications.

As with all invasive procedures, there are inherent risks with IV cannulation and having a well trained workforce, carrying out regular observations and safe use of all products can help reduce these risks. Despite best efforts, and due to external influences such as 'pressures of workload' and 'staff shortages' people are still able to use 'workarounds' and make human errors where they may select and use an incorrect syringe-type, select the wrong product and not follow ANTT procedures. This can lead to a risk of contamination, selection of the wrong syringe-type and may lead to a drug and infusion error.

The availability of the 5 key components relies on users ordering the right products from central stores, selecting the right products from the ward stock room, and preparing and using them correctly.

The organisation's IV and cannulation policy allows for the immediate use of the IV flush and IV medication as long preparation and administration is an 'uninterrupted' process and this also does not require any labelling. However, when more than one syringe is prepared and used [IV medication and IV flush] these unlabelled syringes may be inadvertently placed in the same tray and the wrong syringe chosen [in the wrong order] and this has led to error.

Picture showing;
*** no labelling of IV syringes**
*** no labelling of IV flush**
*** incorrect tray-type**
*** 10ml syringe 'key-part' is not protected from touch contamination**
*** Waste components left in the tray**

Item	Item description	Order via
1	10 mL sterile Luer Slip syringe	Central Stores
2	10 mL ampoule 0.9% sodium chloride	Pharmacy
3	70% alcohol wipe for cleaning ampoule prior to use	Pharmacy
4	18G blunt fill needle to withdraw from ampoule	Central Stores
5	obturator (end stop) to ensure syringe sterility	Central Stores
	(Note: ANTT allows for sterile packaging to be used instead of an obturator to protect key-parts)	

Table 1: components used for manually preparing an IV flush

All practitioners new to the role of peripheral intravenous cannulation…

All practitioners new to the role of peripheral intravenous cannulation are required to complete the Swansea Bay University Health Board's approved peripheral intravenous cannulation training package, and be deemed competent in using ANTT for the insertion of peripheral intravenous cannula. Practitioners for whom the skill has been identified as being required in their role and who have previously been assessed as competent in a different organisations' will also be assessed for competency by an IV cannulation assessor.

The administration of 5 mL for adult (2 mL for small gauge e.g. paediatrics) of 0.9% sodium chloride flush (where compatible) is an integral part of peripheral IV cannulation and ongoing management for IV medications (i.e. pre and post administration flush). In order to maintain standard practice the following volumes are administered using a 10mL diameter syringe to reduce pressure (See table 2).

Note: *The use of a 10mL diameter syringe reduces overall force and pressure when flushing cannula and IV devices.*

Cannula Insertion	Vol	Flushing pre – post IV	Vol
ADULT: IV cannulation (flush)	**5mL**	ADULT: IV administration via cannula	**5mL pre & post**
Small gauge and/or fluid restricted: IV cannulation (flush)	**2mL**	Small gauge and/or fluid restricted IV administration	**2mL pre & post**

Table 2: Volumes for flushing cannula, lines and IV medications.

In all instances, all IV flushes must be checked in line with current employer's policy and the tip of the syringe must be protected from touch-contamination by using either a sterile single- use cap or returned to its original packaging prior to use. ANTT must be maintained throughout this process.

Issues of risk

For all systems of work there are inherent risks, and IV flushing is no different. There are many steps required in current practice when drawing up, preparing and administrating the IV flush. In some instances, this process is also a 2-practitioner procedure as there is additional risk of inadvertent drug selections and dose calculation error.

If following best practice guidelines and ANTT procedures, then a total of 5 separate components will be required to prepare a simple flush of 0.9% sodium chloride for an IV cannula. A new 10ml syringe is required (albeit only 5mL is needed) as the overall diameter of a 10 mL syringe reduces the overall pressure exerted on the vein during cannulation. A new 70% alcohol impregnated swab is requited to clean the neck of the ampoule or vial. A safety drawing up needle [as part of the organisation's safer sharps regulation]. This will need to be a 'filtered' safety needle if using glass ampoules. A sterile obturator to safely cap the prepared syringe, however, the packaging of the syringe can also be used as advised by ANTT procedures and an ampoule of 0.9% sodium chloride. In addition to the inherent risk in preparing the IV flush the time taken to prepare the flush also has to be accounted for.

5 components used to prepare and draw up an IV flush

Wrong route errors are still being recorded in the NHS...

Evidence clearly shows the risk of error and contamination when using separate products and manual draw-up processes and this can be mitigated with a pre-prepared (pre-filled) device. Wrong route errors are still being recorded in the NHS (3), in some cases oral medicines have accidentally been administered to patients' via IV lines and cannula (by using the incorrect type of syringe) and this has further highlighted the risk of manually preparing IV flushes of 0.9% sodium chloride.

When broken down into individual task steps, then a detailed plan can be worked out. Each of the 10 steps pose a potential for human error. Also, as in any clinical procedure there are also risks to the healthcare practitioner, and these include: needle-stick injury and aerosol exposure.

Number of steps required	No. of steps
Steps required to prepare, draw up and label IV flush	10

Using separate products	Risk issues
1. choose syringe and remove from packaging	Selecting wrong type of syringe for process i.e. IV, ENFit, NRFit
2. Open separate blunt-fill* needle packaging and attach to syringe	Selecting wrong type of needle (i.e. filtered, non-filtered, non-safety)
3. Disinfect the sodium chloride 0.9% ampoule (glass/ plastic)	Forget to disinfect ampoule
4. Break the ampoule cover	Risk of glass injury
5. Remove blunt-fill needle cover	Plastic waste
6. Insert needle into ampoule and withdraw sodium chloride 0.9%	Needle stick injury (although limited by use of safety needles)
7. Expel air	Aerosol exposure
8. Remove and dispose of the blunt-fill needle	Disposal via sharps box and cost
9. Attach a sterile cap to the syringe tip (or place back into packaging: ANTT)	No cap available, may lead to touch contamination
10. Write and attach a label to the syringe barrel	Legibility, and not always labelled

*Use filtered needle for glass ampoules

In order to help mitigate risks, and reduce (as far as is reasonably, practicable) then a series of pre-filled syringes of 0.9% sodium chloride for flushing are available in the NHS from a number of different suppliers. These pre-filled syringes come in a variety of different fill volumes (eg. 3, 5 and 10 mL) and as a 'sterile pathway' or fully 'sterile' version for use in surgical ANTT procedures. These devices require no preparation, have a long shelf life and come ready labelled for use.

Regulations and Guidelines.. medicine or device?

Regulations and Guidelines

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK (4). As a general rule, products making medical claims will be regulated either by the medical devices regulations (MDR) or by medicines legislation.

The recent (2017) updated MDR Medical Device Regulations define a **medical device** in Article 2 and this states;

Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

**diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
**diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
**investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
**providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

*....and which does n**ot achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body,** but which may be assisted in its function by such means.*

For **medicinal products** separate legislation and regulations apply:

Article 1 of Directive 2001/83/EC (as amended) [3] defines a 'medicinal product' as:

'*Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to **restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action**, or to making a medical diagnosis'.*

POM (Prescription Only Medicine) or CE marked medical device?

Making the Case

Time:
The time taken to prepare, and draw up 0.9% sodium chloride for IV is estimated to be 48 seconds whereas the same time for a prefilled syringe is only 15 seconds. For 200,000 infusions this related to a time saving of over 1,800 hours of staff time. (@ Band 5 salary = cost saving of approx. £25,000 p.a.). The number of steps required (and chance of error) is greatly reduced and the pre-filled device comes as a ready-to-use sterile product with a minimum shelf life of 3 years.

Placing Orders:
There is only a need to place one order from one supplier as opposed to multiple orders for 5 separate products in the preparation of an IV flush, each pre-filled device barcode traceable for audit purposes.

Needle-stick injury:
The risk of accidental needle stick injury (albeit current practice helps reduce occurrence by using a safer sharp device: i.e. blunt-fill needle) is removed when using a pre-filled syringe as there is no requirement to use, or dispose of a safety needle for drawing up the sodium chloride flush.

Labelling:
The risk of accidentally picking up an unlabelled IV flush syringe and mistaking it for other IV medication is removed; the pre-filled flush syringe (0.9% sodium chloride) comes ready labelled and dated with a clear indication for use resulting in safer systems for patients and staff.

NPSA 20:
The National Patient Safety Agency (NPSA) as far back as 2007 (5) recommended a 'purchasing for safety policy' and move towards 'pre-prepared' infusions and 'ready-to-use' products to help reduce risk of error and harm. The use of a pre-filled, IV flushing syringe can be adopted as part of an organisation's risk reduction strategy in addition to standardising products, procedures and practice.

Safer Sharps:
As part of an organisation's safer sharps project, the implementation of the pre-filled syringe of 0.9% sodium chloride syringe can be recommended. Despite having safer needles (i.e. blunt-fill) this will remove the need to use a needle to draw up the IV flush.

Waste:
Presently, the need to manually draw up the IV flush is achieved by using 5 separate products (each needs to be stocked and disposed of after use). The pre-filled flush syringe has one outer packet plus the syringe itself. Overall cost of waste disposal can be reduced by reducing the 5 separate products to just one.

Adoption of the medical device as an IV flush

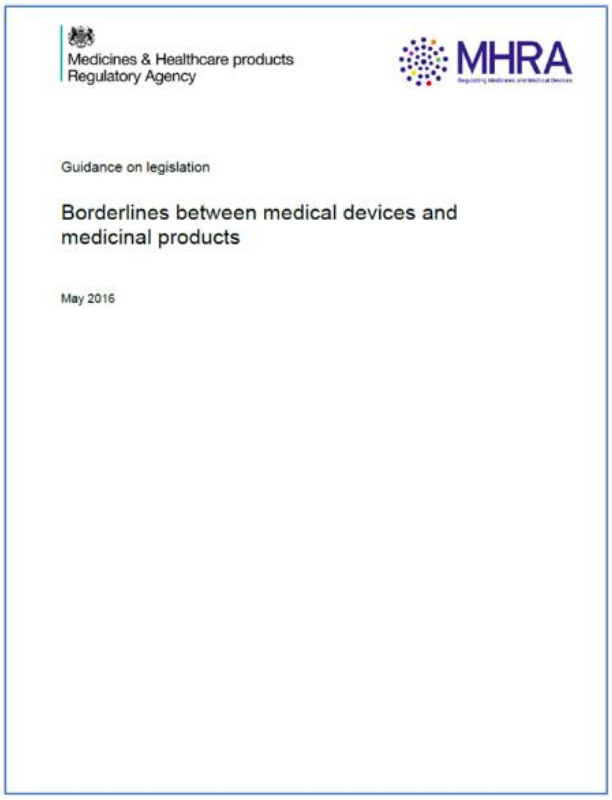
As a pre-filled syringe of 0.9% sodium chloride for flushing IVs carries a CE mark and is regulated as a medical device. The Medicines and Healthcare products Regulatory Agency (MHRA) issued advice around 'Borderline Products' (6) and list these devices under the MDR (Medical Device Regulations). As a result, these products can be stocked and distributed by central stores within organisations. Their purchase is not limited to the traditional pharmacy model as they are not defined and subsequently classified as medicines.

When used as part of the IV process they do not require a prescription or PGD. However, it should be noted that 0.9% Sodium chloride ampoules are classified as a prescription only medicine (POM) and as a result must be prescribed and administered via a prescription, PSD or PGD.

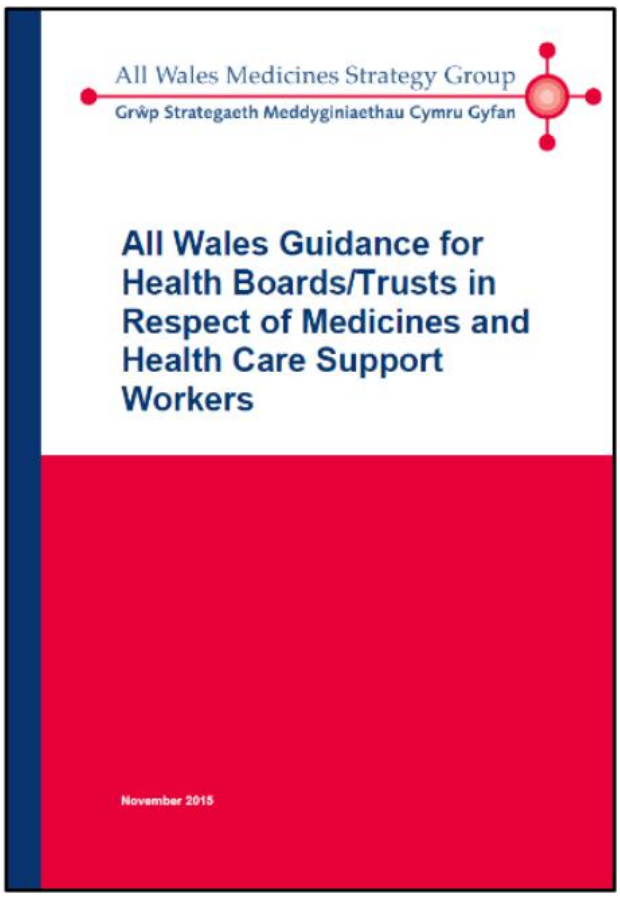
However, a pre-filled syringe, used to flush a cannula is not considered to be a medicine (***as the purpose is not to restore, correct or modify physiological functions***) and therefore comes under the category of 'CE' marked Medical Device and as such can be purchased, stored, managed and used as such.

These are accepted as medical devices provided that they are specifically intended for the mechanical flushing of medical devices such as ports and catheters, even when the flush may result in the fluid entering the body. Such products must be clearly contraindicated for direct systemic administration. Classification will depend upon the ingredients contained in the flushing solution. Pre-filled syringes for systemic administration are always regulated as medicinal products.

In November 2015, an All-Wales joint working group issued guidance around the use an adoption of pre-filled syringes for healthcare support workers. A range of interventions were included and the use of pre-filled syringes for flushing devices was included within this guidance.



Item 36. Pre-filled, single use, syringes specifically intended for mechanical flushing of ports and catheters (saline / heparin etc.)



The UK Picture

As part of a scoping exercise a number of health care organisations were asked in 2019 to share their procedures and guidelines and these helped to develop our bespoke cannulation guidelines. Health care organisations across the UK showed significant variation in management of cannulation flushing. It was clear that some have adopted processes by accepting the MHRA position that they are a CE marked medical device, some have written protocols and some have simply accepted their use as an integral part the IV cannulation and Intravenous administration process, without any further control.

Whilst the NMC are unable to comment on the legal classification or administration of specific products, employers need to seek clarification elsewhere as to the exact nature and classification of pre-filled syringes for flushing IV cannula and lines. This classification will determine whether the device contents can be administered, with or without a prescription, psd or pgd. The fact it is licensed as a medical device, rather than a medical product, means that it does not meet the criteria for classification and subsequent licensing as a prescription-only medicine.

The NMC reminds practitioners that section 18 of the NMC Code (7), which states that all NMC registrants must advise on, prescribe, supply, dispense or administer medicines within the limits of their training and competence, the law, our guidance and other relevant policies, guidance and regulations. If organisations consider a pre-filled syringe for flushing to be a POM (prescription only medicine) then this will have a major impact on the ongoing use, adoption and control of pre-filled syringes for flushing IV lines and cannula in the UK.

If these are considered to be POMs then this precludes registered and any non-registered staff supported by organisation policies and procedures (i.e. healthcare support workers trained in IV cannulation) from using them without appropriate processes being in place. All staff using them will need to get these devices prescribed, checked and documented and this will have an enormous impact on current workloads and practice.

The NMC and MHRA have gone some way to clarify their interpretation and ask all organisations to look at how they purchase, use and prescribe borderline devices to ensure that policies, procedures and guidelines are followed and that they have considered all avenues when choosing to opt for pre-filled syringes for flushing IV cannula.

Conclusion

In Swansea Bay University Health Board, the move to a pre-filled syringe (0.9% sodium chloride) for flushing IV lines and cannulae offers a safer, more cost effective method of flushing compared to the previous 5 separate product approach.

The following safety and risk reduction strategies can be achieved by using pre-filled (CE marked) syringes for IV flushes;

- Reducing the number of products (and waste) required to prepare an IV flush.
- Reducing the number of steps required to prepare IV flushes.
- Saving time required to prepare and draw up each IV flush.
- Reducing the risk of accidental wrong route error as all pre-filled flushes come sterile, capped, labelled and ready for use.
- Removes the risk of needle stick injury.
- Removes the risk of possible contamination of 0.9% sodium chloride ampoules.

This was managed and implemented using risk assessment and quality management methodology. Keeping stakeholders informed and reporting to senior management at every level was key.

The management and adoption of CE marked 'borderline' devices needs to be considered using a multidisciplinary team approach to agree both their use in the clinical setting, their inclusion in cannulation packs, ward ordering and safer IV therapy policy and practice.

References:

1. RCN Standards for Infusion Therapy; https://www.rcn.org.uk/professional-development/publications/PUB-005704

2. EPIC 3 guidelines: https://improvement.nhs.uk/documents/847/epic3_National_Evidence-Based_Guidelines_for_Preventing_HCAI_in_NHSE.pdf

3. Healthcare Safety Investigation Branch 2019: https://chfg.org/hsib-investigation-report-wrong-route-medication-error/

4. MHRA: https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety

5. NPSA Alert 20: https://www.sps.nhs.uk/articles/npsa-alert-promoting-safer-use-of-injection-medicines-npsa-20-2007/

6. MHRA Borderline Devices 2016: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/521420/Borderlines_between_medical_devices_and_other_products__such_as_personal_protective_equipment__cosmetics_and_biocides_.pdf

7. NMC Code: https://www.nmc.org.uk/standards/code/read-the-code-online/

THE MHRA, ADVERSE INCIDENT REPORTING AND ASSISTIVE TECHNOLOGY

Background

The term 'assistive technology' covers a wide range of products. Many are classified as medical devices, coming under the Medical Device Directive [1] and incoming Medical Device Regulations [2], including some of the most widely issued equipment in the health service. Examples include mobility aids (crutches, walking frames, wheelchairs, orthoses, prosthetic limbs etc), devices for manual handling (such as hoists), electronic communication aids and hearing aids.

Most will fall into medical device class I, the category considered to have the lowest inherent risks. Despite this, adverse incidents involving this equipment can cause serious or fatal injuries.

Understanding the performance of devices as they are used in the field is of critical importance to maintaining the safety of these devices and is a key priority for the MHRA. The nature of assistive technology makes this more challenging for the MHRA than for some other device types. For example, since they may be used day-to-day by members of the public or community health organisations and so use and maintenance is harder to control.

Report statistics

In recent years, the MHRA has seen a significant increase in total reported adverse events for medical devices. This can largely be attributed to improvements in manufacturer post-market surveillance. Figure 1 shows this increase: the total number of incoming reports has almost doubled since 2011.

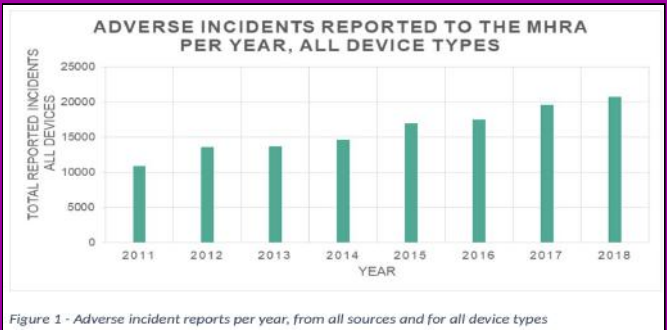


Figure 1 - Adverse incident reports per year, from all sources and for all device types

However, in recent years...

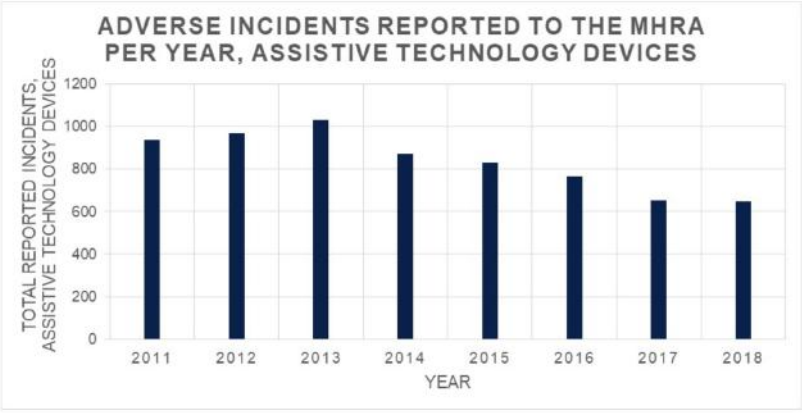


Figure 2 - Adverse incident reports per year, from all sources for assistive technology devices only

However, in recent years, the total number of reports received regarding assistive technology devices has fallen (Figure 2), mostly due to a reduction in reports from professional users.

Some possible reasons for this change in pattern include:

* The quality of medical devices and suitability of prescription is now better, meaning there are fewer problems to report. However, the number of manufacturer vigilance reports has remained consistent over the same time (albeit against a broader trend for manufacturer reports in other areas to increase). The ageing population and prolific prescription of devices also works against this conclusion.

* Reporting to the MHRA may have become a lower priority for clinicians. Local risk management recording is now more established, and any issues may be primarily reported there. With limitations on clinical time, duplication of reporting may have been discouraged.

* The MHRA investigation processes for investigating issues now prioritises identifying trends in incidents. If the investigation process is not clear, then this could have meant that those who may have previously reported issues may no longer do so.

* To address this fall in adverse events relating to assistive technology devices, the MHRA assistive technology group has embarked on a process of re-engaging with key stakeholders to demonstrate the importance of reporting medical device issues.

How Reports Are Investigated

Manufacturers are obliged to investigate and report on incidents where someone was or could have been seriously injured. In some other circumstances (such as for widespread issues and safety related corrective actions) they should also submit a report [3].

The MHRA monitors the progress of corrective actions to ensure that affected users are informed of the issue via the manufacturer's Field Safety Notice and that the corrective action is being applied appropriately.

When the MHRA receives a report from a professional user, it is forwarded to the manufacturer for an investigation to take place. It is therefore very difficult for the MHRA to take any action without information on the manufacturer of the device. Manufacturers should then either complete a detailed investigation or explain why they believe the issue is not formally reportable. If an investigation is required, they will typically need access to the failed device to draw conclusions, so it is important for reporters to retain the device rather than dispose of it whenever possible.

All reports received are added to our database and are available for MHRA staff to perform trending analyses to pick up serious and/or widespread issues.

Actions

If the MHRA believes that a device issue requires additional attention from users, a Medical Device Alert (MDA) can be issued using the Central Alerting System. This is usually done if a manufacturer's Field Safety Notice has not been suitably acknowledged by affected users but may also be issued in response to broader issues. The MHRA also works with the Medical Device Safety Officer network (and other stakeholders) to highlight problems. Longstanding device issues may also be the subject of specific guidance documents (for example [4] regarding the safe use of bed rails).

The Agency also has legal powers to restrict the sale of devices which are found to not comply with the device regulations.

Summary

Understanding performance is key to maintaining the safety of device users. By reporting device problems, clinical professionals can improve patient safety across the country. For more information, please visit the MHRA assistive technology webpage [5].

References

[1] Council Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market [Online]. [Accessed 30 April 2019]. Available from: http://eur-lex.europa.eu/

[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [Online]. [Accessed 30 April 2019]. Available from: http://eur-lex.europa.eu/

[3] MEDDEV 2.12-1 Rev 8 Guidelines on a medical devices vigilance system [Online]. [Accessed 30 April 2019] Available from http://ec.europa.eu

[4] Bed rails: management and safe use December 2013 [Online]. [Accessed 30 April 2019] Available from: http://www.gov.uk/ Medicines and Healthcare Products Regulatory Agency, London UK.

[5] Assistive technology: definition and safe use August 2018 [Online]. [Accessed 06 June 2019] Available from: https://www.gov.uk/government/publications/assistive-technology-definition-and-safe-use/assistive-technology-definition-and-safe-use

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

NATIONAL PATIENT SAFETY TEAM SHARING WITH NAMDET

The National Patient Safety Team are grateful to NAMDET for sharing the following examples of the importance of positive patient identification, at the point of use, when training and educating staff in the use of medical devices.

Example 1

A report received through STEIS concerned POC (Point Of Care) management and the importance of positive patient identification as part of training and/or device installation and set-up. Although the incident referred to a specific device, the sequence of use may be apparent in other POC devices which are configured to transmit data to the electronic patient record.

To summarise, a Point of Care Team received a phone call concerning a patient having numerous glucose results recorded against their electronic patient record, however, they had not been an inpatient for several years. The patient was also not diabetic. Review of evidence showed that staff were selecting the first available patient on the glucose monitor, instead of typing the patient's name or scanning the barcode from the patient's identification label. This led to Incorrect patient identification which also resulted in:

· wrong results matched to wrong patient
· results not transmitted into the correct patient electronic record
· some of the glucose testing results would have required clinical intervention as they were out of range, but those patients were unable to be identified or traced

Similar occurrences were found when reviewing subsequent glucose monitors. The level of harm was unable to be quantified as the patients were not known and therefore the implications for them could not be assessed.

The learning from this was that the device set up allowed the user to skip positive patient identification. The device was reconfigured so use of the 'select patient' function was switched off, leaving only the barcode option available.

We thought this might be useful for NAMDET members to review if their POC devices can be utilised in ways which don't support positive patient identification.

Example 2

Discussion with experts in the field of ECG algorithm software, following an incident reviewed by the patient safety team, revealed a second issue with a similar theme which may be beneficial to incorporate in to education and training for staff performing ECG recording.

This issue relates to the importance of inputting the age and gender of a patient as a minimum, when performing an ECG recording which utilises automated interpretation. Although the trace itself is unaffected, the automated interpretation can be affected if demographics are not input. If the age and gender of the patient are not input to the device, then a default will be chosen: this is usually a male aged 50 because most individuals requiring an ECG are around and above that age and using male, means higher thresholds are used which minimises errors.

When it's not possible to input demographics, a statement should be recorded on the trace/interpretation report which states that automated interpretation was made "without knowing patient's gender/age". Some hospitals use bar code scanning systems attached to an ECG machine (and other medical devices), which will scan the patient ID so that age and gender are input automatically.

Whilst we recognise ECG interpretation by a clinician incorporates many other factors including patient history, symptoms, disease profile etc, the ECG recording only reflects cardiac rhythm at that moment in time. Therefore, if interpretation software is in use, inputting minimum age and gender specifics will provide the optimum profile to support clinical judgement and decision making. We are not advocating reliance on automated interpretation alone but are trying to best support users in their understanding of accurate performance of devices.

Selfie

INSIGHTS

Name: Alastair Jakeman
Age: 55
Daily role / position: Medical Devices Training Coordinator,
York Teaching Hospitals NHS Foundation Trust.
NAMDET role: Secretary for the NAMDET Yorkshire group
Family: Married to Faith.
Children Ellie (22yrs), Beth (22yrs), Tom (22yrs)

Hobbies / interests: Listening to music, hill walking, running, reading, DIY and a growing appreciation for local ale. I am also a Deacon and Secretary of a local church in York.

Why have you got involved in NAMDET?
My boss Keith Underwood told me to ;-) and then I said that I wouldn't say 'no' if asked to be Secretary!

What do you believe NAMDET offers people in your role?
A very helpful local network of experience. I have only been doing this for a bit over 18 months and have been really grateful to local NAMDET colleagues for help with my questions.

What is your working history that led to where you are now?
I came to York in 1982 to do a degree in Chemistry. After that decided I wanted to work with people rather than infrared spectrometers so trained to be a Nurse. After 26 years in A&E , 4 of those as Clinical Educator, I needed a change. Working in A&E gave me an appreciation for the importance of good equipment and the Clinical Educator role reinforced the importance of a properly trained workforce. The new job was an ideal combination of these.

What are your responsibilities?
Along with my boss Keith Underwood (based in Scarborough) we deliver teaching about general medical device safety and train staff on our two main infusion devices as well as organise or help to organise training on new equipment that comes into the Trust. We are part of the Clinical Skills team so are both also involved in teaching on Immediate Life Support courses.

What do you find most challenging in your role?
Disseminating information to staff across a large Trust in numerous locations and getting that information read and acted on is a constant challenge.

What has been your most significant accomplishment in your work?
I enjoy my job very much but nothing can beat my A&E experiences of successfully defibrillating patients who have a VF arrest in front of you.

What things about your work frustrates you the most?
Very little – it's a great job in a great team.

What do you most want those working with medical devices in the NHS to understand?
That our hard work is worth it – medical device safety is an important part of the patient safety agenda.

What changes would you like to see in the NHS relating to medical devices?
I was really struck by the recent Clinical Human Factors Group conference "Safer Healthcare by Design" and I would like to see independent usability testing become mandatory for new equipment before it becomes available to Supply Chain.

What excites or worries you most about Brexit in relation to your work and the NHS and why?
Nothing excites me about Brexit, I don't expect there to be more money available to us as a result of it in fact I expect that there will be significant austerity within the public sector as a result of it. I sincerely hope I am wrong.

Do you believe there is a North / South divide in medical device training and why?
I am not aware of one. We are all in this to make sure that patients are well looked after and I hope that through NAMDET we can learn from each other – this is why a national conference is important.

Beautiful countryside, James Herriot, Yorkshire pudding, decent beer, flat caps, whippets, cricket and rugby league – all things your colleagues around the UK might stereotypically associate with Yorkshire, but what would you like them to know about Yorkshire?

In general:
I am not a native Yorkshireman but you can't help being struck by all the beautiful countryside; The Peak District, the Yorkshire Dales, The North Yorkshire Moors, the Yorkshire Wolds and the fantastic North Yorkshire coastline. But you are right the beer is also great – I would recommend Riggwelter (5.9%) from the Black Sheep Brewery in Masham, they have recently taken over the York Brewery who also make some lovely beer.

From a medical devices / NAMDET perspective?:
There are many hospitals in our region with lots of good hard work going on in all of them and lots of our commercial colleagues busy around our region and beyond training staff on their equipment. We are keen to see more people join us and bring their ideas and experiences to our meetings.

The NAMDET conference is coming to Yorkshire this year. What can delegates expect to see different?
I hope delegates get a chance to see something of the beautiful city of York while they are here or at least a glimpse of the walls as they come out of the railway station – it only takes an hour to go completely round them. The racecourse venue should be really good, we are up a few floors with great views out over the Knavesmire (the open area that the racecourse is on) and we are hoping that there will be more commercial stands than last year let alone some interesting speakers so there will be quite a buzz!

What one piece of advice have you received that you feel has been significant to you and worth sharing with readers?
No one ever said on their death bed "I wish I spent more time in the office." Get a good work/life balance.

What topics would you like to see covered in MDET in the future?
As mentioned above it would be interesting to hear more about medical device usability testing and how we can lobby government to have independent usability testing on new medical devices made mandatory.

If you could be any fictional character, who would you be and why?
Tintin because he has amazing adventures and has a great dog called Snowy! I love the Hergé artwork.

If you had not gone into the career you have, what would you have been instead?
I think I would have been a Civil Engineer – I like motorway bridges and intersections, amazing engineering,

If you were granted three wishes what would they be?

1. To go back to 1974 and hear Genesis perform the whole of The Lamb Lies Down on Broadway live – a progrocker's dream.

2. That Disney had bought the franchise for Star Wars before they made episodes 1 to 3.

3. And on a more serious note, that all governments would take climate change seriously.

What's your favourite book or film and why?
Lord of the Rings by JRR Tolkein because it has some truly and consistently noble characters who, though imperfect, don't waver from what they should do.

What's your favourite song and why?
This is the hardest question! Today I will say 'One' by U2 from their pivotal 1991 album Achtung Baby but tomorrow I might say 'Sabbath Morning at Sea' from Elgar's Sea Pictures. There is so much wonderful music out there!

What/who is the person or thing that has inspired you the most and why?
As a Christian I would clearly say that Jesus has had the biggest influence on me but my family, and especially my wife, are a constant inspiration to me because they are also great examples and willing to question and challenge me.

SAFER HEALTHCARE BY DESIGN

The NHS Supply Chain reflects on a fascinating conference

The Safer Healthcare by Design conference was hosted by the Clinical Health Factors Group (CHFG) at the RCN in London on 12 June. Focusing on the importance of user and clinical input to the design and testing of medical and other devices, speakers offered a range of perspectives on this important subject.

The event was introduced by CHFG founder Martine Bromiley, who formed the group following the death of his wife. He spoke about the need to recognise the difference between 'work as imagined' and 'work as done' when developing devices and equipment. It's the people who actually do the work who really know how processes really work – not safety officers or managers.

A number of interesting points were made during the packed event:

There are 29,500 medical device companies in Europe, but the average number of employees is just two.

Pre-registration approval needs to be done by real staff in a realistic environment and as early as possible.

When mistakes are made we should not automatically blame the user. We need to recognise that this is 'use error' not user error. Manufactures shouldn't hide behind devices that are poorly designed and difficult to use by saying that you just need to read the instructions.

Design will always trump instructions. For example, three different sets of instructions are provided for the use of oxygen masks on aircraft – in the safety leaflet in the seat pocket, during the safety demonstration by staff and on the masks themselves. However, a photo of passengers failing to wear oxygen masks correctly circulated on social media following an incident on an American flight last year, which may well be because masks are the wrong shape.

People assume devices are safe and well-designed because they have already made it onto the market, but user testing has not always been undertaken. There are three potential areas for error prevention – redesigning machines, introducing new systems and or changing human behaviours. Changing behaviour is more difficult but unfortunately can be perceived to be cheaper than redesigning machines.

The NHS Supply Chain's Colette Longstaffe [pictured above] spoke about the Clinical and Product Assurance Framework which assures the process of stakeholder engagement and product evaluation undertaken as part of the new service model. The process aims to ensure that products available through NHS Supply Chain are safe, fit for purpose, where possible innovative, and representative of the needs of health and care professionals, other staff, patients, carers, and other users. The Clinical and Product Assurance (CaPA) team also has oversight of complaints and address all patient safety in addition to working collaboratively across other health and social care organisations to align national strategies and direction of travel.

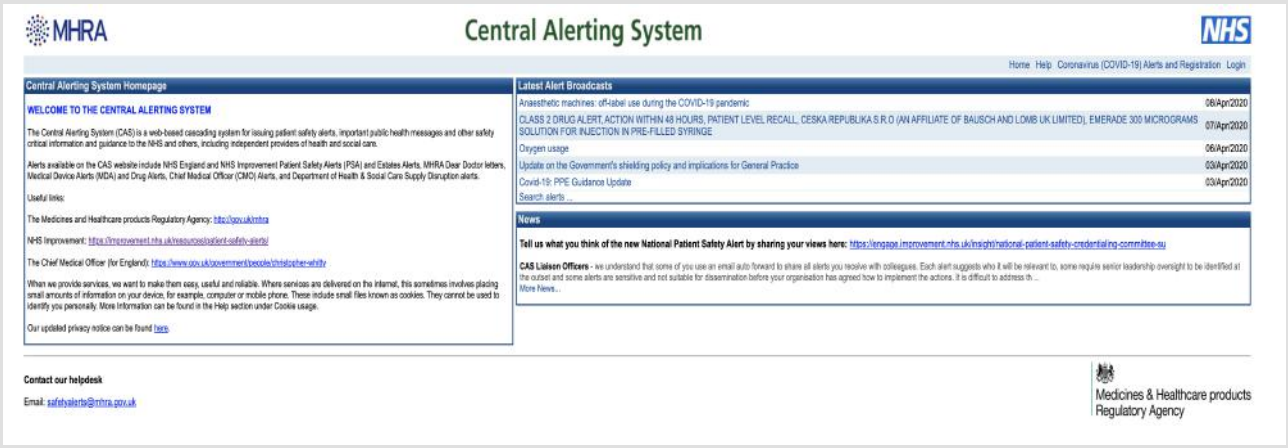
The procurement of medical swabs is one example of the importance of clinical engagement. After an issue was identified with fraying and loose x-ray tracing strips, CaPA worked with Clinical Nurse Advisors, service providers and trusts to identify an alternative product which took into account how the product is used in practice.

CaPA's input is also important where there are no mandatory standards for a product, which can be the case with non-medical devices, resulting in variation of quality and potential patient safety issues.

All in all the combination of interesting insights and examples of good practice, delivered by people passionate about their subject, made for a thought-provoking day.

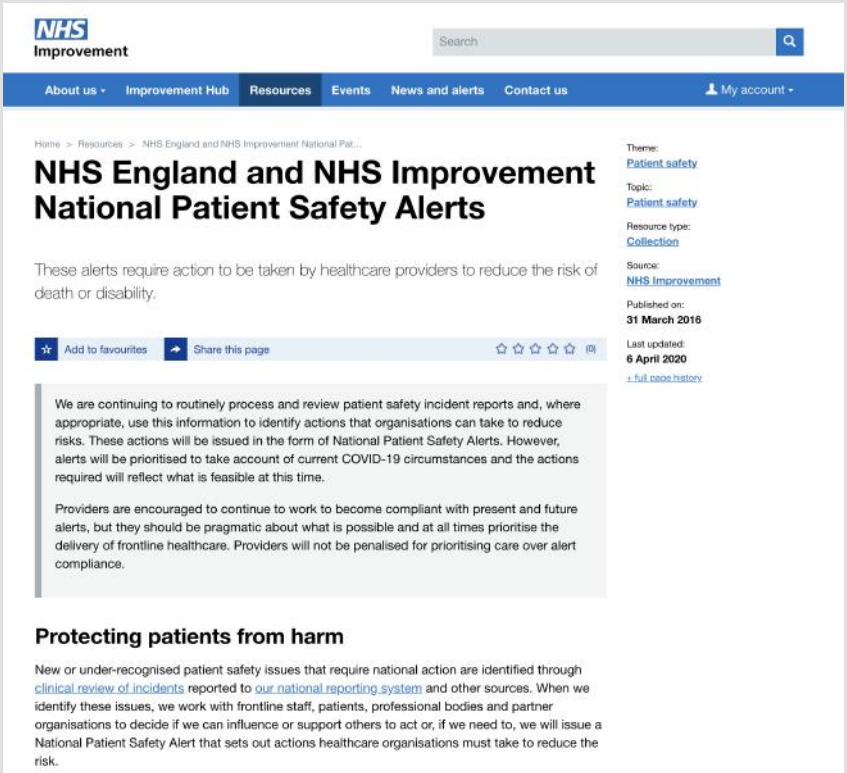
MEDICAL DEVICE NEWS

The Central Alerting System (CAS) still holds valuable links and updated safety alerts, warnings and patient safety advice for all medical device trainers and MDSOs (Medical Device Safety Officers). Here's a 'snapshot' of some of the ones issued over the past few months since our last MDET edition. For the full alerts and complete list please make sure you go directly to the CAS website and review all alerts for devices, medications and drug alerts too.



Our colleagues in NHS England and NHS Improvement also have an up to date website for important news, safety features and alerts too. Their National Patient Safety Team regularly report on new and emerging issues and share their new national alerts via this portal.

Please check out their website for the latest news, and safety alerts to



MEDICAL DEVICE NEWS

Important alerts and safety updates you might have missed include:

NatPSA/2019/003/NHSPS. 13th December 2019. Risk of harm to babies and children from coin and button batteries in hearing aids and other hearing devices

MDA/2019/046 Issued: 19 December 2019. Arrow EZ-IO intraosseous vascular access needle sets – risk of needle stick injury

MDA/2020/001. 15th January 2020. NIPPY ventilators (all models) - update to user instructions.

MDA/2020/003 :28 January 2020. Professional use defibrillator/monitor: all HeartStart XL+ (Model number 861290) - risk of failure to deliver therapy

MDA/2020/005: 5th February 2020:t Slim X2 insulin pumps, discard or destroy defective mains (A/C) power adaptors

MDA/2020/007 25th February: T34 and T34L syringe drivers. Addressing the issue of 'wear and tear' of the motor block which may cause under infusion and no alarm. Check before each use

MDA/2020/009 27th February 2020: Tympanic Thermometers form Cardinal Health around the calibration frequency for Genius 2 and 3. (revised to every 25 weeks)

Estates and Facilities Alert. NHSE/I – 2020/001 Issued: 31 March 2020. Use of high flow Oxygen therapy devices (including wall CPAP and high flow face mask or nasal oxygen) during the Coronavirus epidemic – urgent patient safety notice; immediate attention required

NatPSA/2020/002/NHSPS. 1st April 2020. Interruption of high flow nasal oxygen during transfer Some staff may assume devices have an internal battery and do not realise how rapidly the patient is likely to deteriorate with even brief interruption of HFNO

NatPSA/2020/003/NHSPS. Blood control safety cannula and needle thoracostomy for tension pneumothorax. Date of issue: 02 April 2020. staff may select a blood control (closed system) cannula not realising its limitations for this procedure

NHS England and NHS Improvement Estates and Facilities. Issue date:06-Apr-2020: Advice on increased demand on Oxygen systems

MDA/2020/012 Issued: 08 April 2020: Anaesthetic machines: off-label use during the COVID-19 pandemic.

CAUTION: These are just a snapshot of the alerts and notices from the CAS website. Please make sure you check out the CAS website [and any national safety websites] regularly and review all alerts and notices for medical devices used in your area.

Thank you from all of us at BD UK & Ireland

1030 Eskdale Rd, Winnersh Triangle, Wokingham, Berkshire, RG41 5TS

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