University Hospitals of Derby and Burton NHS Foundation Trust

TRUST POLICY FOR THE MANAGEMENT OF AMBULATORY SYRINGE DRIVERS FOR SUBCUTANEOUS USE ON ADULTS

Reference Number From Library and Knowledge Service Manager	**Version:** V3	**Status** FINAL	**Author:** Carol Busch **Job Title:** Medical Equipment Officer

Version / Amendment History	**Version**	**Date**	**Author**	**Reason**
	V1 RDH	2010	Mark Cannell,	Review
	V1/2 QHB	2017	Unknown	National Alert
	V3	2023	C Busch	New Trust-wide Policy

Intended Recipients: All clinical staff, Associate/Executive Directors, Divisional and Operational Managers.

Training and Dissemination: Training is provided for all identified clinical and medical staff in clinical areas as identified in local training needs analysis. Dissemination via the Trust Intranet

To be read in conjunction with: Risk management - Trust Policy and Procedure, Incident Reporting, Management and learning - Trust Policy and Procedure, Decontamination of reusable Medical Devices - Trust Policy and Procedure, Medical Devices Competency and Training Requirements Connected with - UHDB Trust Policy and Procedure, Continuous Subcutaneous Infusions (CSCI) - Preparation of - Standard Operating Procedure (SOP) -

In consultation with and Date: Pharmacy; Palliative care; Medical Devices Group - 4 October 2023

EIRA stage One Completed Yes
stage Two Completed NA

Approving Body and Date Approved	Trust Delivery Group - December 2023
Date of Issue	December 2023
Review Date and Frequency	September 2026 - Every 3 years
Contact for Review	Carol Busch (Medical Equipment Officer)
Executive Lead Signature	 Garry Marsh, Executive Chief Nurse

Contents

1.Introduction

An integral part of any life is its end, Professional Codes and Moral Standards, make it imperative that this part of care has clear outlines and process to ensure that recipients and family feel their needs are best catered for.

Ambulatory Syringe Drivers are commonly used for administration of drugs via the subcutaneous route. This allows the consistent delivery of one or more medications for effective symptom management. A syringe driver delivers the medication(s) for periods of up to 24 hours at a time This policy refers only to drugs being delivered via the subcutaneous route.

In 2010The UK National Patient Safety Agency (NPSA) issued a Rapid Response Report (RRR019) on the safer use of ambulatory syringe drivers, see appendix 1. The report warned of the risk of errors using the ten common older types of ambulatory syringe drivers; these used rate settings in millimetres (mm) of syringe plunger travel rather than in drug volume (millilitres, mL). The report included evidenced failings in many devices on the market that had led to eight deaths (four in 2009) and 167 non-fatal error reports between 2005 and 2010.

This policy exists to clarify the requirements of the Trust and staff in their "Duty of care", its' need to manage its assets and the compassionate delivery of care, from within current legislation and in response of this call to action.

2. Purpose and Outcomes

Provide a link between the clinical process of sub-cutaneous drug delivery and the management of devices used for this at UHDB.

To provide guidance to the users of these products, on how the Trust will manage and optimise its limited resources to provide this service to all that need it.

To reemphasize the points about the device in use and future devices for this use in all age ranges (from the lessons learnt in RRR019),

3. Definitions Used

Ambulatory Syringe Driver: Ambulatory infers the product is to be used while the Patient goes about their normal daily activities. The device therefore needs to be simple and small, easily portable, and internally powered (battery or otherwise). It should be able to deliver prescribed drugs, at a predetermined rate by near continuous subcutaneous infusion.

The UHDB currently uses syringes to hold the medications - drug reservoir. The "Syringe Driver", works by slowly pushing the plunger of the syringe which in turn, pushes the fluid containing medication(s) into an administration set. The set is connected to the patient, and into the subcutaneous tissue, via a sub-cutaneous cannula.

A Medical Device: is defined by the MHRA (Medicines and Healthcare products Regulatory Agency) (Managing Medical Devices. April 2014) as any product used in the diagnosis, treatment, prevention or alleviation of illness or injury, of a patient.

Clinical Equipment: are mostly powered (and mostly reusable) Medical Devices, requiring Maintenance and Service as per manufacturer's instructions. These individual items must be recorded separately for governance and maintenance reasons.

Consumables: are mainly "Single Use Medical Devices", these are often very low-cost, high-volume products, occasionally associated with specific Clinical Equipment (then known as Dedicated Consumables). As low cost is often bought directly by clinical areas, as part of their revenue spends.

Single Use Medical Devices: All devices that are for "single use" or single patient use will not be re-used within the Trust.

Trust Equipment Library: A central storage and management area for commonly used devices and associated consumables. This Trust-wide approach has repeatedly been demonstrated as more efficient and effective in the provision of services in a lean and risk laden environment such as healthcare.

Trust Equipment Database: there will be one sole source of information relating to the inventory of Trust Clinical Equipment.

Device Labelling: To ensure that the ownership and user requirements for Service and Maintenance are easily understood.

4. Key Responsibilities/Duties

4.1 **The Chief Executive**
The Chief Executive has overall responsibility for the use and management of medical devices within the Trust.

4.2 **UHDB Trust Board**
The Trust Board will seek independent assurance that an appropriate and effective system of managing medical devices is in place and that the necessary levels of controls and monitoring are being implemented.

4.3 **The Executive Medical Director**
The Medical Director is the nominated Executive Director for medical devices and has Board level responsibility for ensuring that there is clear and effective monitoring of all aspects of medical devices management, and that the Trust follows relevant legislation and Department of Health guidance with regards to medical devices.

4.4 **The Executive Chief Nurse**
The Executive Chief Nurse is the nominated Executive Director for Risk Management and has Board level responsibility for ensuring that there is clear and effective monitoring of all aspects of Risk Management associated with medical devices.

The Executive Chief Nurse is also the nominated Safety Alert Broadcast System (SABS) liaison officer for the Trust. Responsibility for ensuring that safety information relating to medical devices is disseminated throughout the organisation, and acted upon accordingly, is delegated

to the Patient Safety and Risk Managers.

4.5 **Corporate Nursing** (incorporating "Risk & Governance", "Patient Safety" and "Equipment Library" Teams)

Corporate Nursing provide the resource of the incident recording systems for the Trust, receiving reports of incidents involving medical devices within the Trust, and work with specialist staff from all departments to investigate incidents and report findings. They are also the holder of the Trust Risk Register that includes details of identified risks associated with medical devices.

They receive and facilitate the Safety Alert Broadcast System (SABS)/Central Alerting System (CAS) information and alerts which are disseminated throughout the organisation. This includes all the National Patient Safety Alerts (NatPSA). They also act as a point of contact and record for the sizeable number of Field Safety Notices (FSA) from Manufacturers.

They promote awareness, via risk updates, training, and other targeted awareness – promoting the importance of the procedures for reporting adverse incidents, and those involving medical devices. Also working (In conjunction with Human Resources) to ensure staff are adequately trained in Health and Safety procedures and the application of safe working practices when using medical devices.

4.6 **Clinical Engineering**

They provide acceptance of all new clinical equipment into the Trust, and on-going maintenance and repair of clinical equipment and maintain a service history for all devices. Providing technical investigation of incidents involving medical devices and ensuring any engineering actions required by safety alerts are implemented. Providing advice on viability of ongoing support for equipment and the engineering need for replacement. Safe decommissioning and disposal of equipment and ensuring cleansing of all personal identifying data.

4.7 **Medical Devices Safety Officer**

The Trusts nominated Medical Devices Safety Officer, will liaise closely with the Medicines Safety Officer and Risk Services to ensure prompt and appropriate responses to Safety Alert Cascade Notifications and act as the Trust connection with the MHRA on device related incidents and learning. They are also a member of the National Medical Devices Safety Network as required by MHRA and NHS England Patient Safety Alert NHS/PSA/D/2014/006 'Improving Medical Device Incident Reporting and Learning'. See UHDB Management of Safety Alerts Policy for detail.

4.8 **Medical Devices Training**

Medical Device Training of authorised users is managed in a consistent and pragmatic way within the Trust, using a risk assessment process to identify equipment requiring significant assurance and specialist users only. This will link with procurement and Device safety. This will be managed and reported as per Policy.

Please see Medical Devices Competency and Training Requirements Connected with - UHDB Trust Policy and Procedure.

4.9 **Medical Equipment Library's**

The Trust's Equipment Library systems provide nationally recognised efficient use of common

equipment across the Trust. In hand with this standardisation approach are cost savings in procurement. The system also allows for limited consumable rationalisation and management. Function and activity are reported through the MDPUG (Medical Devices and Product User Group) on exception.

The Equipment Library Team, with Procurement, and the Medical Device Engineering teams manage, regulate and support day to day equipment purchasing and standardisation.

4.10 **Divisional Directors**
These individuals report to the Trust Board and the Chief Executive via the Chief Operating Officer. They are managerially responsible for the function of the Clinical Divisions, their Business Units and Wards, and are responsible to the Trust Board (Via MDPUG and MDG (Medical Devices Group)) for the compliance of their staff to this, and associated Policies.

4.11 **Business Unit Management**
These Groups (Management, Nursing and Medical) report the Divisional Boards, responsible for the function of their subordinate service areas (Wards and departments) and are responsible to their respective Divisional Board for the compliance of their staff to this, and associated Policies. This includes responsibilities for the inventory (and assistance in the upkeep of that inventory at Trust level) of medical equipment in their area.

4.12 **Ward and Departmental Management**
These teams report the Business Unit Management; they are responsible for the function of their direct areas (Wards and departments) and are responsible to their respective Business unit Board for the compliance of their staff to this, and associated Policies. This includes responsibilities for the inventory (and assistance in the upkeep of that inventory at Trust level) of medical equipment in their area.

4.13 **Users**
This definition relates to authorised users of Clinical Equipment, this is detailed in the Medical Devices Training Policy, which includes all Trust Clinical Staff (Doctors, Nurses, Allied Health Professionals, and non-trained support workers), Bank and Agency staff working in these roles, and Carers and Patients. This includes responsibilities for the medical equipment directly in their control.

4.14 **Medical Device Groups**
A hierarchy of Device related groups exist in the Trust to assure levels of adoption of the policies and that the governance is embedded.

4.14.1 **Medical Devices Group (MDG)**
This is a subgroup of Finance and Information Committee and receives escalations from MDPUG. The bids for Capital Equipment are debated and challenged in this forum. The links to Estates Prioritisation and Change in Clinical Practice forums are formal, and often bids require authorisation from at least 2 of these forums.

4.14.2 **Medical Devices and Product User Group (MDPUG)**
This is a division and business unit linked group, reviewing Training and Maintenance compliance levels and action plans. Non-compliance is an escalation to MDG. This group has close links to Decontamination Groups and management, also with the operational Procurement meetings. This forum takes reports and monitors the Operational policies, such

as the Loans Protocols, Company Representative codes of conduct, Medical Devices Training Policy. The group manages the identification of standard products for supplies masking of consumables and recommendations to MDG of Standardised Clinical Equipment.

5 The Process for Control of the Risks Associated with the Management of Ambulatory Syringe Drivers

This can be separated into 3 main parts:

- assurance of the compliance of the product with RRR019,
- effective use by clinical staff,
- efficient availability at the point of care.

The initial aspect of this policy is the requirement is to fulfil the national expectation of a process for the assurance that whatever device is used for this activity that it is fit for its intended purpose. This links to the Trust's Medical Devices Management policy, where the specification and procurement methods are indicated, and the specifications identified within from RRR019 would be met (appendix 1).

For the proper understanding, and for competent and safe use within the care environments, staff must adhere to the Medical Devices Competency and Training Requirements Connected with - UHDB Trust Policy and Procedure. Any specifics of the therapy are covered under care-dependant training, i.e., Palliative Care, Parkinson's and Respiratory. Derbyshire has a joint policy for I*nformal* Carer's Administration for As Required Subcutaneous injections in Community Palliative Care.

As the UHDB supports fast-track discharge, syringe drivers owned by the Trust are sent out with patients to avoid any delay to discharge. To allow this to continue and so we have the functioning stock, these are issued via the UHDB Equipment Library. To facilitate this, simple rules are in place.

Requirement	Rationale
All staff in the use areas are trained in the use of the device and therapy	Effective care meets not only the moral duty of staff, and the human rights of the patient, and with cognitive use of this information can enhance the patient and family experience. Meeting Legal responsibilities under the "Care act", H&S Legal requirements, CQC and Professional standards.
All products related to this therapy and loaned from the Equipment Library, must be fully booked out. This includes Area, Patients details and importantly an accurate Hospital Number.	All products cost money to replace, the pumps themselves are a significant outlay. For them to be replaced the Medical Devices department needs to know if they are lost or beyond use, this is a process requirement. For continued availability of this service the products involved must be traceable. If we are sending these devices out with patients, we need to be able to retrieve them – the most efficient way is to have an accurate Hospital Number. Practice is that Patients are discharged home with Trust Assets, and these are meant to be returned (under ICB (Integrated Care Board)) within 48hours. We do not have sufficient data without full booking to ensure return of the products and thus availability for the next patient. The Trust has a requirement to be able to recall items if reported as a patient risk or faulty by the National Patient Safety Agency (NatPSA Safety Alerts).
All products are returned after single patient use	To ensure our care and therapy meet the basic standards (CQC and H&S) our Products must be returned after each patient, the utilisation within a Healthcare environment is vital to the products, needing a set of safety checks and enhanced decontamination, with a chance of early detection of faults. The enhanced probity of the products provides an improved service longevity. Upon return items are checked to see that they are in a safe working condition. Any repairs or servicing of the device are reported and returned to Engineering. Upon completion the devices are logged back into the library ready for use.
All users use approved consumables	It is essential for safe and proper therapy that the correct and approved consumables are used. This includes batteries and Syringes.
Infusion therapy checklist is used whilst in Hospital.	Requirement of Infusion Therapy Guidelines

6. Monitoring Compliance and Effectiveness

Monitoring Requirement:	• Health and Care Act 2022 • The Medicines and Healthcare Product Regulatory Agency (MHRA) document 'Managing Medical Devices – April 2021 • IEC (International Electrotechnical Commission) International Standard 62353:2014 'Medical Electrical Equipment – Recurrent test and test after repair of medical electrical equipment' • Health and Safety at Work Act 1974 • PUWER (Provision and Use of Work Equipment Regulations 1998) • CQC(Care Quality Commission) Regulation 9: Person-Centered Care • CQC Regulation 10: Dignity and Respect • CQC Regulation 11: Need for Consent • CQC Regulation 12: Safe care and Treatment • CQC Regulation 17: Good Governance • CQC Regulation 18: Staffing
Monitoring Method:	The MDPUG will monitor a number of metrics via reports from Divisional and Business unit representation as fixed agenda items, this will include: • Medical Devices training compliance and action plans • Medical Device servicing compliance and action plans • Equipment decontamination compliance • Equipment Library use and returns compliance • Safety Alerts response compliance and action plans • Incidents relating to medical devices reporting
Report Prepared by:	Chair of MDPUG
Monitoring Report presented to:	Exception Escalation to MDG ad hoc Replacement program to MDG ad hoc. Monthly Medical Devices Group, to F&IC
Frequency of Report	Monthly

7 References

References – related/further reading.

1) The CQC New Inspection Framework. Care Quality Commission, 2023.
2) NHSLA. Risk Management Handbook, 2013/14. NHS Litigation Authority, March 2013.
3) NHSLA Risk Management Standards for NHS Trusts providing Acute, Community or Mental Health & Learning Disability Services and Independent Sector Providers of

NHS Care, 2011/12. NHS Litigation Authority, January 2011.
4) Medical Electrical Installation Guidance Notes, (MEIGaN) (2007), Medicines and Healthcare Products Regulatory Agency, London
5) Single-Use Medical Devices: Implications and Consequences of Reuse MHRA DB2006(04) v2.0
6) Management of In Vitro Diagnostic Medical Devices MDA DB2002(02) Medical Devices Agency, London
7) Reporting Adverse Incidents and Disseminating Medical Device Alerts MHRA /2004/001. Medical Devices Agency, London
8) Safeguarding Public Health: The Medical Devices Regulations: Implications on Healthcare and other related Establishments Bulletin 18. Medicines and Healthcare products Regulatory Agency (2003), London
9) Managing Medical Devices: Guidance for Health and social Care Organisations. Medicines and Healthcare products Regulatory Agency (MHRA), January 2021
10) The Management of Medical Equipment in NHS Acute Trusts in England National Audit Office (1999), London
11) For The Record - Managing records in NHS Trusts and Health Authorities HSC 1999/53 1999 NHS Executive
12) BS EN 60601-1:2006 Medical Electrical Equipment, General Requirements for Basic Safety and Essential Performance
13) IEC 62353:2014 'Medical Electrical Equipment – Recurrent test and test after repair of medical electrical equipment.
14) Health and Safety at Work Act HMSO 1974 ISBN 0 10 543774 3
15) Safe Use of Work Equipment, Provision and Use of Work Equipment Regulations 1998. Approved Code of Practice and Guidance L22 HSE (Health and Safety Executive) Books 1998 ISBN 0 7176 1626 6
16) Electricity at Work Regulations 1989 SI (Serious Incident) 1989/635 HMSO 1989 ISBN 0 11 096635 X
17) Health and Care Act 2022
18) Guidance on protecting connected Medical Devices. NHS Digital, October 2022.
19) Safer Ambulatory Syringe Drivers, NPSA Dec 2010
20) Derbyshire Policy for Informal Carers Administration of As Required Subcutaneous Injections in Community Palliative Care, internal Link from KOHA

8. Appendices

8.1 Appendix 1: RRR019 Safer Ambulatory Syringe Drivers

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.

NHS Evidence accredited provider

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.**

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