STANDARD OPERATING PROCEDURE
THE SAFE ADMINISTRATION OF DALTEPARIN (FRAGMIN), TINZAPARIN, ENOXAPARIN FOR PROPHYLAXIS TREATMENT ONLY IN THE COMMUNITY BY NON-REGISTERED STAFF

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CHANGE RECORD

Version	Date	Change details
1	Oct 2019	New SOP
1.1	Oct 2021	Update / review Approved through DTG 31 March 2022

Contents

1. INTRODUCTION

Background

Venous thrombosis is a condition in which a blood clot (thrombus) forms in a vein. Blood flow through the affected vein can be limited by the clot, causing swelling and pain in the affected limb or area. Venous thrombosis most commonly occurs in the 'deep veins' in the legs, thighs, or pelvis.

This is known as a deep vein thrombosis. An embolism is created if a part or all of the blood clot in the deep vein breaks off from the site where it is created and travels through the venous system. If the clot lodges in the lung a very serious condition, pulmonary embolism (PE), arises, which can be life threatening. Venous thrombosis can form in any part of the venous system. However, deep vein thrombosis (DVT) and PE are the most common manifestations of venous thrombosis. DVT and PE are known as venous thromboembolism (VTE).

Patients should be fully informed, NICE Guidance (NG89) 1.2.4 notes that as part of the discharge plan, give patients and their family members or carers (as appropriate) verbal and written information on:

- the signs and symptoms of deep vein thrombosis (DVT) and pulmonary embolism
- how people can reduce their risk of VTE (such as keeping well hydrated and, if possible, exercising and becoming more mobile)
- the importance of seeking help if DVT, pulmonary embolism or other adverse events are suspected.

2. SCOPE

This SOP describes the safe and effective procedure for administering injectable Low Molecular Weight Heparin (LMWH) in a prefilled syringe for prophylaxis treatment by non-registered clinician where the task is delegated from a registered clinician to a non-registered clinician. It includes both registered and non-registered clinicians that are permanent, temporary, bank or agency staff excluding students within the community setting employed by Humber Teaching Hospital NHS Foundation Trust.

It is aimed at non-registered clinicians involved in the administration of LMWHs **for prophylaxis treatment only**. It aims to cover all indications for the prevention of venous thromboembolism. It is applicable to all patients who are to receive a LMWH for prophylaxis and have been discharged from hospital, are still under the routine care of community services clinician.

- To ensure safe, reliable and effective patient care based on best practice
- To reduce the risks/complications associated with poor practice.
- Staff undertaking this procedure must be able to demonstrate full competence in accordance with Trust policy, having completed the prescribed training and assessment.
- This SOP is to be used only in conjunction with approved clinical skills training. The administration of a subcutaneous anticoagulant injection should not be delegated to non-registered clinician unless the assessment is complete, and all parameters are positive. The assessment forms should be completed by the HCA and assessor before competency is deemed complete. Annual reassessment using the reassessment form will be required. The Registered practitioner in charge of the caseload should ensure that the non-registered clinicians records are assessed and validated.
- Where care is delegated to a non-registered clinician, the registered clinician remains accountable for the appropriateness of the delegation and care delivery. They are also

responsible for the overall management of the patient care that includes a regular review of the care or immediate if there are any concerns

3. DUTIES AND RESPONSIBILITIES

Matrons
Supports and enables operational clinical leads to fulfil their responsibilities and ensure the effective implementation of this document.

Managers/Clinical Lead and Team Leaders
Responsible for ensuring that staff have access to this SOP and other relevant SOPs and policies, as well as training and support.
Ensures the provision of training and support to the non-registered clinician to deliver the element of care / task and complies with all relevant trust policies and SOPs.
Responsible for ensuring that individual's competencies are implemented, achieved, and maintained.

Registered Clinician
Will be accountable for the delegation of any aspects of the administering injectable low molecular weight heparin and ensuring the individual is competent to carry out the task (NMC 2018) (HCPC 2016) and is in the best interest of the patient. This includes ongoing assessment and supervision of practice, regular review of the patient or for immediate review if there are any concerns.
Will ensure that their knowledge and skills are maintained and be responsible for maintaining standards of practice.

Non-registered Clinician
The non-register practitioner must not undertake the element of administering injectable low molecular weight heparin until they have been assessed as competent by the named registered practitioner and completed the required eLearning/ training, live supervision, and competency assessment. Once trained and assessed as competent they will undertake the delegated task of administering injectable low molecular weight heparin. They will ensure that their knowledge and skills are maintained and be responsible for maintaining standards of practice. They will undertake the trust approved training and meet the competencies required for the element of administering injectable low molecular weight heparin.

They will participate in ongoing clinical and management supervision and assessment by a registered practitioner, including observed practice. They will escalate concerns relating to a registered practitioner, who will be always accessible.

INFORMED CONSENT

The registered practitioner must obtain informed verbal consent to the delegation of the task from the person receiving care, or where that person does not have the capacity to give consent, the principles of the Mental Capacity Act (2005) should be followed as set out in the Consent Policy (N-052) and Mental Capacity Act (2005).
The registered practitioner must ensure that the person's mental capacity is kept under review. They must ensure that the non-registered clinician has an awareness of the Mental Capacity Act, can recognise when mental capacity may have been lost, and are obliged to liaise with them if they have any concerns about the person's capacity to consent.
The non-registered clinician is responsible for the duty to obtain ongoing consent every time care / treatment is performed.

Where a person receiving care lacks capacity, the non-registered clinician has a duty to act in their best interests. An assessment of best interests should be undertaken by the registered practitioner

If consent is refused, care and treatment should not be delegated. The refusal should be documented and reported immediately to the delegating registered nurse on duty, and the person's GP (or prescriber) must be informed.

DELEGATION, RISK AND PROFESSIONAL JUDGEMENT

The ability of the non-registered clinician to carry out the administering prefilled injectable low molecular weight heparin including their pre-existing knowledge should be determined by the registered practitioner. Delegation is not mandatory and choosing to delegate duties to an individual is subject to the discretion and judgement of the registered practitioner. Non-registered clinician have a right to refuse to take on a delegated responsibility should they not feel confident or competent to do so.

The NMC Code are clear that registered practitioners can delegate activities to another person, provided they are satisfied that the person has received adequate training and are assured that they are competent to perform the task. Under the NMC code the registered nurse remains accountable for the tasks they delegate. Delegation should only occur under the best interests of the patient.

It is vital that the register practitioner makes sure the non-registered clinician can access advice and guidance from them on a regular basis (e.g., monthly clinical supervision and regular huddles to discuss patient specific cases as part of a mentoring relationship - and the ability to access immediate advice when there are any concerns to enable provision of safe and compassionate care.
Where there is a break in practice, e.g., an individual has not been using their skills for more than three months, for example during a career break or maternity leave, then a refreshed certificate of e-Learning and updated competency assessment is required, before the delegation of duties to the non-registered clinician can recommence.

Should there be an incident, error or near miss, the registered practitioner should consider what training and further supervision the non-registered clinician may require or if the frequency of monitoring/reassessment should increase.

Personalised care plan
Delegated elements of administering prefilled injectable low molecular weight heparin must not be carried out without the completion an individualised care plan/support plan and evidence that the delegated non-registered clinician has been assessed as competent to undertake the delegated task of administering injectable low molecular weight heparin.
The registered clinician must complete a comprehensive assessment and record of care, and identify the condition of the person receiving care as predictable. There must be clear arrangements for timely access to the registered practitioner for advice and guidance if/when the person receiving care's condition deviate from what is normal for them.

Plan of Care must explicitly indicate that the care can be delegated to a non-registered clinician and the frequency for review by a registered clinician.

Processes must be in place to flag the date(s) when reassessment of competence of the non-registered(s) clinician is due this will be highlighted on ESR. Competence of the non-registered clinician to carry out a specific intervention should be reassessed annually or more often if required. If the staff member has not visited the patient in the last month a review will be needed

Low Molecular Weight Heparins (LMWHs)
LMWHs are used in the 'prevention' of VTE (prophylaxis) in patients at moderate to high risk and are given in a low dose. LMWHs are also used in the 'treatment' of VTE in patients who develop a DVT or PE and are given in a higher dose but these are excluded from this SOP.

There are a number of LMWHs licensed for both prevention and treatment of DVT/PE in the UK. These include DALTEPARIN (FRAGMIN), TINZAPARIN, ENOXAPARIN These are types of heparin – a low molecular weight heparin – and belongs to a group of medicines called anticoagulants
These medicines affect how your blood clots.

- prevents clotting, allowing normal blood flow through the arteries and veins.

They are used to:

- Prevent blood clots in adults before and after an operation.
- Prevent blood clots in adults who have an increased risk of blood clots e.g. due to an acute illness with limited mobility.

Contraindications
Heparin should not be used in:

- with low numbers of blood cells called platelets in their blood (thrombocytopenia)
- who have previously developed a reduced platelet count due to treatment with heparin
- actively bleeding
- peptic ulcer
- very high blood pressure
- bacterial infection of the heart valves and lining surrounding the heart (bacterial endocarditis)
- cerebral haemorrhage

Side effects
Medicines and their possible side effects can affect individual people in different ways. The following are some of the side effects that are known to be associated with this medicine.it does not mean the people using this medicine will experience a side effect.

- Bleeding
- High blood potassium levels (hyperkalaemia)
- Decrease in number of platelets in the blood (thrombocytopenia)
- Break down of skin cells
- Thinning of bones with long term use (osteoporosis)
- Hair loss with prolonged use

The side effects above may not include all the side effects reported by the manufacturers

Requirements of Registered nurses
Community nurses should check the following before administering a dose of LMWH

- Indication – whether prophylaxis or treatment
- Duration of treatment
- Weight of patient
- Renal function

Prescription for LMWH
Ensure prescription for Low Molecular weight heparin is completed as per policy.
Prior to administration the non- registered clinician must ensure:

- The correct patient
- The correct drug
- The correct dose
- The correct date and time
- The correct route and method of administration
- The validity and legibility of the prescription

- The signature of the prescription/instruction
- The non- registered clinician will explain the procedure to the patient and obtain consent.
- The non- registered clinician will safely and accurately administer the medication by the route intended following infection control and the safe disposal of sharps policies.
- The non- registered clinician will record batch numbers and expiry dates of medications used within the patient record as per Record Keeping Standards.

Monitoring

For patients receiving a LMWH for longer than 5 days, the following should be monitored:

- Platelets — this is due to the risk of antibody-mediated heparin-induced thrombocytopenia.
- Monitor platelets approximately 7 to 10 days after initiation and then 3 monthly whilst LMWH treatment continues. Treatment should be stopped immediately in those who develop thrombocytopenia.
- U&E monitoring -this is required if the patient is having treatment for longer than 7 days and is at greater risk of hyperkalaemia due to e.g. diabetes, CKD, taking potassium-sparing diuretics (spironolactone, amiloride, eplerenone).

4. PROCEDURES

Action	Rationale
This Standard Operating Procedure for subcutaneous injected low molecule heparin to be implemented in the Community setting in patients' homes	To be carried out by trained Health Care Assistants and registered Nurses who have undertaken competency training and assessment working within their scope of practice.
Confirm patients' identity as per Trust policy and ensure it corresponds with the Medicines administration chart/prescription.	To ensure correct patient
Ensure diagnosis, reason, request and frequency for subcutaneous injected low molecule heparin is evident – Check System 1 patient Record.	
Ensure recent blood results are checked and parameters have been set	
Explain the procedure to the patient.	To ensure informed patient consent given.
Assess the patient fitness and understanding to engage in the procedure, ensure they are aware of both the benefits and risks of heparin.	VTE prophylaxis. Risks include, bleeding, abscesses and lipohypertrophy (accumulation of fat under the skin) due to frequent injections within the same area of skin
Ensure patient consent is given and documented as per Trust policy. Be aware that heparins are of animal origin and this may be of concern to some people, if so refer back to GP. Where patient capacity is deemed compromised please refer to Mental Capacity Act.	For patient to understand the risks and benefits of the planned procedure prior to giving consent as per *Consent Policy and Mental Capacity 2005 and Deprivation of Liberty safeguards Policy*

Action	Rationale
Check that the patient is feeling well, has any concerns, any bleeding and bruising, calf pain/tenderness or inflammation or shortness of breath if so refer for immediate medical review, commence NEWS 2 assessment and escalation which may need to be emergency 999	To assess patient for any signs of side effects, deterioration and to ensure patient safety.
Ensure privacy and dignity during the procedure.	As per trust Privacy and Dignity policy
Check the prescription is present and correct and follow the 'five rights' of medicines administration: • Right patient (Patient name, DOB, NHS number, address) • Right drug • Right time • Right dose • Right route Also: Commencement date Prescribers name and signature End date	To ensure patient safety and ensure the correct administration of medications in line with national and local Medicines Management policy
Check for Allergies (if there is a discrepancy in what the patient says and what is documented do not give the drug, consult with the prescriber) and for any previous side effects caused by heparin	To ensure patient safety and avoid potential anaphylaxis. In the event of anaphylaxis **999** commence action as per the trust Anaphylaxis guideline treatment and management of individuals who present with suspected anaphylactic reactions standard operating procedure for management of anaphylaxis kits in the community team Medical Emergencies and Resuscitation Policy and Procedure (M-004)
Ensure the patient is positioned comfortably in either a supported sitting/semi-recumbent or lying position.	To support patient safety
Wash and dry hands	To reduce risk of infection Utilisation of appropriate PPE and adhere to ANTT compliance as per Aseptic Non touch technique Policy, Hand Hygiene Policy

Action	Rationale
Select and expose puncture site, checking that it is healthy, free of oedema, infection or lesions.	Ensure free of infection, skin lesions, scars, birthmarks, bony prominences, and large underlying muscles, blood vessels or nerves (Dougherty and Lister, 2015).The amount of subcutaneous fat varies between patients, individual patient assessment is vital before carrying out the procedure. Recommended sites for subcutaneous injection include the lateral aspects of the upper arm and thigh, and the umbilical region of the abdomen (Ogston-Tuck, 2014; Hunter, 2008).
Only prescribed pre-loaded Heparin syringes with an integral safety needle device should be used. Remove pre-filled syringe and adhere to manufacturer's instructions, check the integrity of the syringe for damage/leakage and/or discolouration, if so do not use. Check drug identification, dose and expiry date is evident on the syringe. Take it to the patient, along with a sharps bin to allow immediate disposal.	
Wash hands. If required were Gloves/PPE Check the skin is visible clean, if in doubt swab for 30 seconds with isopropyl alcohol and then allow to dry for 30 seconds. Inform the patient that you are now going to perform the injection.	To reduce risk of infection. Utilisation of appropriate PPE and adhere to ANTT compliance as per Aseptic Non touch technique Policy, Hand Hygiene Policy. WHO (2010) suggested that if a patient is physically clean and generally in good health, swabbing of the skin before injection is not necessary However in the elderly or immunocompromised patients, skin prep with 70% isopropyl alcohol should be considered on patient assessment as would the use of gloves/PPE.
Using you dominant hand hold the syringe and with your other hand pinch the skin at the chosen site free from the underlying muscle, do not expel the air bubble from the preloaded syringe unless indicated in the manufactures instructions. Insert the needle as per the manufacture's instructions in a dart-like motion. Drawback is not necessary. Depress the plunger and inject the drug slowly as per the manufacturer's instructions To avoid site bruising do not massage puncture site, Release pinched skin	The lifted skinfold technique (pinching or bunching the skin) can be used to lift the subcutaneous layer away from the underlying This method reduces the risk of inadvertent intramuscular injection when undertaken correctly; however, releasing the skin too quickly before the injection is completed or lifting it incorrectly can increase that risk

Action	Rationale
Do not attempt to resheaf the exposed needle, activate safety device, Immediately dispose of sharps directly into the correct sharps bin and close as per policy.	Safe removal and avoidance of needle stick injury. If incurred action as per Management of Injuries from Contaminated Sharps Policy and Datix
Ask the patient if they are comfortable, observe for any side effects, if the patient becomes unwell, perform baseline NEWS2, if faints/unresponsive commence **ABCDE/999**	To ensure patient comfort and wellbeing
Remove PPE and wash hands.	To reduce risk of infection
Sign the prescription chart	To ensure adherence to treatment plan
Document procedure including site and any variance uncounted.	To ensure procedure appropriately recorded in line with defensible documentation.
Ensure the patient/relative have received an advice information leaflet, and verbally remind the patient • What to do if site bleeds • What to do if feeling faint • When to have next blood test Any concerns to contact their senior nurse /General Practitioner	Promote patient safety

5. REFERENCES

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NG89 Assessment of risk of VTE in a Community Setting 2020