Royal Devon University Healthcare NHS Foundation Trust

Title:

Genetic Haemochromatosis

Reference Number: RDF1276
Date of Response: 03/01/2023

Further to your Freedom of Information Act request, please find the Trust's response(s) below.

Please be aware that the Royal Devon University Healthcare NHS Foundation Trust (Royal Devon) has existed since 1st April 2022 following the integration of the Northern Devon Healthcare NHS Trust (known as Northern Services) and the Royal Devon and Exeter NHS Foundation Trust (known as Eastern Services).

I am writing to you under the Freedom of Information Act 2000 to request the following information from you.

a. For the period 1st January 2022 to 31st December 2022 (or the most recent 12-month period available), the number of patients diagnosed with genetic haemochromatosis under your care.

The Trust total of patients diagnosed with genetic haemochromatosis is 498.

b. For the period 1st January 2022 to 31st December 2022 (or the most recent 12-month period available), the average time in days from first referral from primary care to the patient's first appointment within your trust.

The Trust is unable to answer Q2 of this FOI. There is no way of knowing which referral (if the patient had multiple) was linked to this diagnosis and if patients were referred because Genetic Haemochromatosis was suspected, or it was a secondary finding. Outpatient appointments do not have diagnosis codes attached and we would not know why a patient was referred without looking at the individual notes or sometimes free text if entered at all. To try to identify if the requested information is held would require the manual extraction and manipulation of information from various sources. To carry out this work would exceed the appropriate cost limit as set out in Section 12 (1) of the Freedom of Information Act 2000 and is therefore exempt.

Under the Freedom of Information Act 2000 Section 12 (1) and defined in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004, a public authority is not obliged to comply with a request for information if it estimates that the cost of complying would exceed the appropriate limit. The limit of £450 represents the estimated cost of one person spending two and a half days in determining whether the Trust holds the information, locating, retrieving, and extracting that information.

c. A copy of your protocol and/or patient pathway applicable to the care of people with genetic haemochromatosis.
d. The date that your protocol/patient pathway for genetic haemochromatosis was last reviewed or revised.

In response to questions c and d - The role of Peninsula Clinical Genetics is in the genetic testing of individuals with hereditary haemochromatosis and their relatives. We follow the 2016 European Molecular Quality Network best practice guidelines available here: (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4929861/pdf/ejhg2015128a.pdf) and via the Exeter Genomics Laboratory webpage: (https://www.exeterlaboratory.com/genetics/haemochromatosis/) – page last updated June 2021.

We are in the process of reviewing our guidance as part of South West Genomic Medicine Service Alliance transformation work. Revised pathways will be available on Devon Formulary when finalised, likely later this year.

Genetic testing eligibility is covered by the Genomic Test Directory (https://www.england.nhs.uk/wp-content/uploads/2018/08/rare-and-inherited-disease-eligibility-criteria-v4.pdf), which is updated regularly.

The most recent version is October 2022. The relevant test codes are R95 (for someone with symptoms of hereditary haemochromatosis) and R244 (carrier testing for known familial mutations) when cascade testing relatives.

e. A copy of your clinical protocol(s) for therapeutic venesection.
f. The date that your protocol(s) for therapeutic venesection were last reviewed or revised.

In response to questions e and f for this FOI. Please find attached Trust non - current SOPS. Please note this SOP is being updated and will be completed by the end of May 2023.

Venesection

Document reference number	SOP-GEN-NUR-017
Post holder responsible for Procedural Document	
Author of Standard Operating Procedure	
Division/ Department responsible for Procedural Document	Specialist Services / Cancer Services
Contact details	Quality Assurance Co-ordinator,
Date of original standard operating procedure	07/02/2008
Impact Assessment performed	Yes / **No**
Approving body and date approved	Cancer Services Governance Group 12/02/2020
Review date (and frequency of further reviews)	01/09/2022 (every 3 years)
Expiry date	11/02/2023
Date document becomes live	12/02/2020

Please *specify* standard/criterion numbers and tick ✓ other boxes as appropriate

Monitoring Information		**Strategic Directions – Key Milestones**	
Patient Experience		Maintain Operational Service Delivery	
Assurance Framework		Integrated Community Pathways	
Monitor/Finance/Performance		Develop Acute services	
CQC Fundamental Standards - Regulation**:**		Infection Control	
Other *(please specify)*:	FACT- JACIE 6th Edition. March 2015.		
Note: This document has been assessed for any equality, diversity or human rights implications			

Controlled document
This document has been created following the Royal Devon and Exeter NHS Foundation Trust Development, Ratification & Management of Procedural Documents Policy. It should not be altered in any way without the express permission of the author or their representative.

Version:		**Status:** Final	
Version	Date	Author (Title not name)	Reason
1	06/2011		Minor changes to front page to include CQC stds. Change to Governance route.
2	09/09/2015	Lead Cancer Nurse	Routine review and hyperlinks added.
3	05/04/2018	Sister Yarty Ward	Addition of blood form for GP bloods and appointment card with next venesection date, blood form/Medway label, updated hyperlinks throughout. Updated Trust SOP template.
4	04/11/2019	Sister Yarty Ward	Routine review. Minor amendments.

Associated Trust Policies/ Procedural documents:	Standard Infection Control Procedures and Policy (including hand hygiene) Waste Management Policy Venous Access Device policy and Procedures Infection Prevention and Control Policy Inoculation (Contamination) Incident Policy
Key Words:	
In consultation with and date: Matron Yarty Ward – November 2019 Sister Yarty Ward – October 2019 Senior Nurse – November 2019 Cancer Services Governance – 12/02/2020	
Contact for Review:	Matron Yarty Ward
Executive Lead Signature:	

CONTENTS

1. PURPOSE

1.1 To ensure a standard procedure exists for peripheral venesection in haematology patients.

2. SCOPE

2.1 This procedure describes the standard arrangements for the general aspects related to venous access. It applies to all nurses caring for haematology patients who have received the appropriate training and are deemed competent to undertake this procedure.

3. DEFINITIONS AND ABBREVIATIONS

3.1 A venesection is the purposeful removal of blood for therapeutic purposes, 200-500mls may be withdrawn.

3.2 **FBC -** Full Blood Count

3.3 **HSE -** Health Service Executive

3.4 **SOP** - Standard Operating Procedure

3.5 **IV -** Intravenous

4. DUTIES AND RESPONSIBILITIES OF STAFF

4.1 It is the responsibility of the **Haematology Matron** to ensure that Haematology nurses are aware of the contents of this SOP.

4.2 It is the responsibility of all **nursing staff** to

- familiarise themselves with the contents of this SOP, sign the comprehension confirmation sheet (Q-Pulse Ref: F-HDCP-QMP-012) and adhere to the content
- undertake training and competency assessment, as required

5. EQUIPMENT AND DOCUMENTATION

5.1 Manual BP machine

5.2 Tourniquet

5.3 Venesection Record Sheet (Q-Pulse Ref: F-NUR-012)

5.4 Disposable sharps bin

5.5 Sani-cloth CHG2%

5.6 Blue plastic tray or similar

5.7 Venesection bag (dry) with needle

5.8 Micropore tape

5.9 Toppers gauze squares

5.10 Blood form/Medway label and relevant blood sample bottles, if required

5.11 Scales

5.12 Blood form for GP bloods and appointment card with next venesection date

5.13 Dressing

5.14 Cannula, if required

5.15 IVI fluid replacement and line, as required

6. PROCEDURE

6.1 Indications for Peripheral Venesection include:

- Haemachromatosis
- Polycythaemia
- Iron overload - Raised ferritin levels due to multiple blood transfusions

6.2 **Note**: On initial decision that venesection is required as treatment; the Consultant Haematologist will document the frequency of venesection and parameters. (Patient may need IV fluids, - consider cardiac pre-screens) The patient will also be given written information and counselled by an appropriate nurse. (See Ref 1 for basic principles regarding venous access)

6.3 FBC is to be taken prior to or on every visit and checked by a clinician or advanced nurse practitioner prior to the venesection taking place**.** Ferritin is normally taken every third visit for frequent venesection treatments and every three months for patients receiving maintenance venesection. The lab will only perform a ferritin test every 2 months, so patient notes must be consulted before requesting a test. Confirmation of volume of venesection should be confirmed with the clinician or advanced nurse practitioner (ANP) on each visit.

6.4 Discuss the procedure with the patient, consulting them as to their choice of arm for venesection, or problems they may have experienced before; do they have allergies associated with the equipment used? Explain the risks/hazards such as coagulation disorders.

6.5 Perform the procedure using a clean non-touch technique and adhere to the Trust's Standard Infection Control Procedures and Policy (including hand hygiene).

6.6 Discuss with patients who have previously undergone venesection whether they required IV fluid or oral fluid replacement. For patients who are undergoing this procedure for the first time, they will require careful monitoring of their blood pressure. If required, cannulate as per the Procedure for Insertion of a Peripheral Venous Cannula and commence IV hydration of 500ml normal saline as prescribed.

6.7 Prepare and cleanse a tray or trolley as per hospital IV guidelines and take it to the patient's bedside and assemble equipment within easy reach. Ensure there is adequate lighting, and place any blood bottles in the correct order of draw.

6.8 Place the patient in a supine position with their arm extended and comfortably supported.

6.9 Check the patient's blood pressure and pulse before the procedure and document on the Venesection Record Sheet (Q-Pulse Ref: F-NUR-012).

6.10 Prior to palpating and selecting a vein, clean your hands carefully as per Standard Infection Control Procedures and Policy (including hand hygiene). It is not unusual for the nurse to locate the best vein by touch and sight initially and to glove up after this has been achieved.

6.11 **Sites to avoid include:**

- Hard flat knotty veins
- Compromised limbs (following surgery or a Cerebral Vascular Event)
- Oedema
- Infection/Broken Skin
- Bruised/Thrombus areas
- Lymphoedema
- Dialysis fistulas

6.12 Apply blood pressure cuff above the selected site and ask the patient to make and hold a fist.

6.13 Palpate to locate the vein. Even if the vein is visible, palpation is necessary to confirm location, direction and suitability of the vein.

6.14 Once the best vein has been located, remember not to leave the BP cuff in place for more than two minutes if it is fully inflated.

6.15 Clean the patient's skin and the selected vein for at least 30 seconds using a Sani-cloth; allow to dry. Do not re-palpate the vein or touch the skin.

6.16 Gel hands and apply non-sterile gloves in accordance with Trust guidelines. (Standard Infection Control Procedures and Policy (including hand hygiene))

6.17 Remove the needle from its packaging and remove the needle guard, inspecting the device.

6.18 Anchor the selected vein by placing your non dominant thumb 1-2 inches below the intended venesection site and secure the needle with micropore.

6.19 Perform the venesection with the bevel of the needle up and inserted at approximately a 10-20 degree angle, in line with the vein and advance 1-2 cm into the vein.

6.20 A rapid, short spurt of blood will be seen in the connecting tube once this has been achieved successfully. Secure the needle with a transparent dressing/micropore tape.

6.21 Reduce the pressure in the BP cuff to 50-60 mmHg.

6.22 Ask the patient to open their fist as soon as blood flow is established; observe the patient throughout the procedure.

6.23 N.B If the patient shows any signs of dizziness or nausea, has a fall in blood pressure or a rise in pulse during the procedure, stop the procedure and elevate the foot of the bed. The medical team must be notified immediately.

6.24 Lower the level of the bag depending on flow of blood but the level of the bag should be below the heart.

6.25 The collecting bag should be placed on the blood scales and monitored until the venesection volume is reached.

6.26 The BP cuff may now be released fully.

6.27 Apply a gauze swab over the site and gently withdraw the needle.

6.28 Apply digital pressure until the bleeding stops; the patient may apply this pressure if they wish to do so. A tourniquet may be used to assist in stopping the bleeding.

6.29 Apply a gauze dressing and tape firmly in place and ensure that the patient is comfortable.

6.30 Clamp the venesection bag to prevent leakage of blood.

6.31 Dispose of sharps and blood bag in a sharps bin as per Trust Waste Management Policy. Under NO circumstances is the blood bag etc. to be given to the patient even though they might request it.

6.32 Check the patient's blood pressure and pulse after the procedure and document this, noting any symptoms of concern and reporting them to the medical team.

6.33 Discard all waste into appropriate waste disposal containers. (Waste Management Policy)

6.34 The patient should be told to rest until they feel perfectly normal, and offered refreshments. They should be advised to drink at least two extra cups of liquid during the day.

6.35 Ensure that the patient has a return appointment and advise them to contact Yarty Day Case Unit if a problem arises after they leave the department.

6.36 Give the patient a blood form for a blood test at their GP surgery prior to their next venesection appointment and an appointment card for their next appointment.

6.37 Document the procedure in the nursing notes by completing the Venesection Record Sheet (Q-Pulse Ref: F-NUR-012).

6.38 As standard we remove 500mls per venesection, unless directed otherwise by the medical staff.

6.39 Deviations from procedure

Deviations from this SOP must be documented in the patient's notes and on Datix.

7. SAFETY CONCERNS

7.1 Nothing in this procedure is intended to override safe working practices and anyone in doubt should consult with their immediate superior.

Risk	-	LOW	possible occurrence/minor injury
		MEDIUM	frequent occurrence/minor injury

HIGH major injury

HAZARD	RISK	MEASURE
Body fluids	Low	All staff must follow safe practice for dealing with biological materials as stated in the RD&E NHS Foundation Trust Waste Management Policy, Section 4.1, 4.2. There are no significant additional hazards or special instructions relating to the process or activities within this procedure.
Inoculation Injury	Low	Staff comply with Trust Venous Access Device policy and Procedures and if injury occurs, with Trust Inoculation (Contamination) Incident Policy.

8. TRAINING AND COMPETENCY OR COMPREHENSION ASSESSMENT

Type of Training	Supervised Procedure
Method of competency assessment for "procedure"	Competency Study Pack
List Staff required for Training and Competency Assessment	Nursing staff identified by Matron as being required to undertake procedure
Who is to perform this training	Self-study followed by supervised procedure.
Evidence Log of Training / Competency Assessment	Before using this SOP, all users must complete the Comprehension Confirmation Form.

9. ARCHIVING ARRANGEMENTS

The original of this SOP will remain with the Quality Assurance Co-ordinator, Cancer Services. An electronic copy will be maintained on Q-Pulse with a link to the Trust intranet, Y – Yarty Ward and Day Case – Procedures, Forms and Clinical Protocols. Archived electronic copies will be stored on the Trust's "archived policies" shared drive, and will be held indefinitely. A paper copy (where one exists) will be retained for 10 years.

10. PROCESS FOR MONITORING COMPLIANCE WITH AND EFFECTIVENESS OF THE PROCEDURE

10.1 Frequency

The Yarty Ward Matron and Quality Assurance Co-ordinator will audit SOPs on a rolling programme as set up on Q-Pulse to ensure compliance and effectiveness of the procedure, a formal report will be written and major non-conformities presented to the Stem Cell Quality Management Group.

10.2 Recommendations/ Action Plans

Implementation of the recommendations and action plan will be monitored by the Stem Cell Quality Management Group, which meets quarterly.

10.3 Any barriers to implementation will be risk-assessed and added to the risk register.

11. AUDITABLE OUTCOMES

11.1 A clinical audit of this SOP will be carried out by nursing ward management (such as

a non-intrusive observation audit of nursing staff practice).

12. REFERENCES

Royal Marsden Hospital Manual of Clinical Nursing Procedures 9th Edition, March 2015

Control of Substances Hazardous to Health Regulations (2002), London: HSE.

13. ASSOCIATED TRUST POLICIES

Standard Infection Control Procedures and Policy (including hand hygiene)

Waste Management Policy

Venous Access Device policy and Procedures

Infection Prevention and Control Policy

Inoculation (Contamination) Incident Policy

APPENDIX 1: COMMUNICATION PLAN

Royal Devon and Exeter NHS
NHS Foundation Trust

The following action plan will be enacted once the document has gone live.

Staff groups that need to have knowledge of the guidance/SOP	Haematology nursing staff who have been trained and competency assessed.
The key changes if a revised document	Routine review with minor amendments.
The key objectives	This procedure describes the standard arrangements for the general aspects related to venous access. It applies to all nurses who have received the appropriate training and are deemed competent to undertake this procedure and who are required to care for haematology patients
How new staff will be made aware of the procedure/guideline and manager action	Ward induction.
Specific Issues to be raised with staff	
Training available to staff	Learning & Development Service run courses for nurses. The venepuncture training required by staff using this SOP is undertaken by the Lead Haematology Nurse
Any other requirements	
Issues following Equality Impact Assessment (if any)	N/A
Location of hard / electronic copy of the document etc.	A hard copy of this SOP will remain with the Quality Assurance Co-ordinator. An electronic copy will be maintained on Q-Pulse with a link to the Trust intranet.

Venesection Competency Framework (Adult)

	Name	Role	Date
Competency Prepared by:		Sister Yarty Ward	09/04/2018 Reviewed October 2021
Competency Checked by (Senior Manager):		Lead Cancer Nurse	07/10/2021

	Name of Group	Date
Ratified by Speciality/Divisional Governance Group:	Cancer Services Governance Group	07/10/2021

	Approval Date	Review Date
Approved by RDE Competence Group:	11/10/2021	11/10/2024

Aim or Purpose of Competency:
• For the Practitioner to demonstrate good communication skills which will enable them to gain informed consent, reduce patient anxiety thus ensuring good compliance throughout the venesection procedure. • For the Practitioner to perform venesection in line with the Trust's guidelines/policy/SOP. • For the procedure to be carried out safely, ensuring unnecessary trauma and with due regard for the patient's comfort. • To ensure that staff are knowledgeable and can provide evidence of competence to safely undertake venesections.
Underpinning References : Baxter Healthcare - www.baxterhealthcare.co.uk (2018) Medline plus - www.nlm.nih.gov (2018) Medic8 - www.medic8.com (2018) Netdoctor - www.netdoctor.co.uk (2018) Infection Prevention and Control Policy (2015) Identification of Patients Policy and Procedure (2018) Waste Management Policy (2017)
Assessor Criteria
• Experienced Haematology Advanced Nurse Practitioner, Ward Matron, or Ward Sister

Entry Criteria and any pre-requisites :
• Registered Nurses and non-registered clinical practitioners within the Haematology department – this must be agreed by the ward Matron on an individual basis. • All staff undertaking this role will need to ensure that they have read the standard operating procedure prior to completing the competency. • To keep up to date with continued professional development.

Learning Contract:

Learner: I confirm that I will comply with the following responsibilities:

- Acknowledge and accept own limitations
- Familiarise myself with relevant Trust and Department protocols and policies.
- Understand legal and ethical implications of role development.
- Work within my own Code of Professional Practice
- Utilise all resources which are made available for learning and professional development
- Understand the demands and needs of the service
- Be able to receive constructive feedback
- Ensure that agreed timeframes are set and met.

Name of staff learning the competence	Role	Signature	Date
			DD/MM/YYYY

Mentor/Assessor: I confirm that I will comply with the following responsibilities:

- Provide time and support for the learner
- Signpost the learner to relevant research and information to support evidence based practice
- Facilitate learning and practice
- Provide constructive feedback.

Name of Mentor/Assessor	Role	Signature	Date
			DD/MM/YYYY

Manager: I confirm that I will comply with the following responsibilities:

- Ensure the competence is appropriate and required for the department/specialty
- Ensure the learner has the appropriate entry requirements
- Ensure the mentor has the appropriate qualification/occupational competency
- Ensure time is allocated to learners training

Name of Manager	Role	Signature	Date
			DD/MM/YYYY

Venesection Competency Framework (Adult)

Outcomes: The learner will…

- Understand the anatomy and physiology of the veins
- Recognise and understand the need for venesections
- Perform venesections following agreed protocols and procedures
- Carry out pre, during and post monitoring and care of the patient undergoing venesection
- Be able to recognise and respond to adverse reactions
- Safely assess patients for adverse reactions
- Advise on the ongoing care
- Liaise with the consultant as to adverse reactions and possible need for treatment changes.

Assessment Table:

Standards - The competent practitioner will be able to:	Date Level (1-5)	Comments
Follows guidance in SOP & policy to safely carry out procedure.	DD/MM/YYYY	
Confirm that the patient has been assessed by a Haematology Advanced Nurse Practitioner (ANP) or Consultant/Specialist Registrar regarding: • *full blood count within therapeutic range* • *Ferritin level, patient to be further assessed if above required level set by consultant* • *Patient is fit for the procedure*	DD/MM/YYYY	

Assessment of the patient, re: • *Blood results (therapeutic range)* • *Blood pressure* • *Physical condition e.g. any contraindications* • *?any recent infection*	DD/MM/YYYY	
Identifies all potential risks or complications associated with venepuncture and venesection. State action to be taken to minimise each of the above, and what action to take if they should occur.	DD/MM/YYYY	
Demonstrates knowledge of the following in relation to venesection: • *The patient's condition/diagnosis* • *Range of blood tests required* • *Ability to select and prepare the appropriate equipment required* • *Safe and correct disposal of equipment* • *Frequency of venesection*	DD/MM/YYYY	
Demonstrates the ability to identify a suitable vein for a safe venesection procedure.	DD/MM/YYYY	
Demonstrates correct technique in skin cleansing, safe needle insertion and connection to appropriate equipment.	DD/MM/YYYY	

Understands the need for obtaining correct volume/weight of blood for procedure.	DD/MM/YYYY	
Applies appropriate dressing over venesection site following the procedure.	DD/MM/YYYY	
Demonstrates the correct labelling of samples and the relevant forms.	DD/MM/YYYY	
Assesses patient's condition during procedure.	DD/MM/YYYY	
Follows up with clinical observations – BP.	DD/MM/YYYY	
Advises patient of immediate follow up care.	DD/MM/YYYY	
Records information correctly in patients' documentation including reporting effectively any adverse reaction recognised.	DD/MM/YYYY	
Observes patient dignity and privacy.	DD/MM/YYYY	
Communicates well with patient, explaining the procedure and answering questions.	DD/MM/YYYY	

Venesection Competency Framework (Adult)

(On successful completion: Complete the Summative sign off sheet attached)

Assessment of Competence

The Mentor/Assessor must complete the assessment table based on the following levels of competence:

Level	Description
1	Knows nothing about the skill.
2	Doubts knowledge and ability to perform the skill safely, without supervision.
3	Could perform the skill safely with supervision.
4	Confident of knowledge and ability to perform the skill safely.
5	Could teach knowledge and skills to others and can demonstrate initiative and adaptability to special problem situations.

(Hodge.R 2003, Clinical Competencies for cardiac nursing, SDDHT)

Summative Sign-off Sheet:

Name of staff achieving the competence	Role	Signature	Date
			DD/MM/YYYY

Name of Mentor/Assessor	Role	Signature	Date
			DD/MM/YYYY

Name of Manager	Role	Signature	Date
			DD/MM/YYYY

We hereby confirm that …… has achieved the above competence.

Review Date ……

(Please keep a copy in the learner's personal file on completion)