Alder Hey Children's NHS
NHS Foundation Trust

Reference Number: FOI202223/576
From: Other

Date: 06 February 2023

Subject: The number of patients diagnosed with genetic haemochromatosis

Q1 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.

A1 Information exempted under Section 40: Personal data. Providing this information would likely identify individuals involved.

Q2 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, for patients diagnosed with genetic haemochromatosis.

A2 Information not held - no patients referred in the last year with haemochromatosis

Q3 A copy of your protocol and/or patient pathway applicable to the care of people with genetic haemochromatosis.

A3 Information not held – we do not have a protocol or patient pathway as this disease is rare

Q4 The date that your protocol/patient pathway for genetic haemochromatosis was last reviewed or revised.

A4 Information not held – as per A1 above

Q5 A copy of your clinical protocol(s) for therapeutic venesection.

A5 Please see attached document: Venesection v1.0 - Draft_Redacted

Please note, the attached document is in draft form.

Staff names exempted under Section 40: Personal Information. Although the information relates to their public role and accountability for managing budgets, disclosure of names of all individuals may potentially have adverse consequences to the employees. Any names of staff that are available in the public domain are accessible via our website https://alderhey.nhs.uk/

Q6 The date that your protocol(s) for therapeutic venesection were last reviewed or revised.

A6 Please see attached document: Venesection v1.0 - Draft_Redacted

Please note, the attached document is in draft form.

Staff names exempted under Section 40: Personal Information. Although the information relates to their public role and accountability for managing budgets, disclosure of names of all individuals may potentially have adverse consequences to the employees. Any names of staff that are available in the public domain are accessible via our website https://alderhey.nhs.uk/

The Trust is unable to respond to all or specific elements of your request where the response would indicate five or less individuals. The Trust is withholding this information under Section 40 (Personal Information) of the Freedom of Information Act (FOIA) 2000 to reduce the risk of any individuals being identified. The Trust is of the view that disclosure of such information would significantly increase the risk of individuals being identified and as such would constitute a breach of their personal data.

The Trust has applied exemption Section 40(2) of the FOIA and is therefore withholding the information as disclosure which may identify an individual would breach their rights under the Data Protection Act 2018. The grounds for application of this exemption include:

- Any data relating to patients or staff is third party data, furthermore health data is classified as sensitive personal data within the Data Protection Act 2018. As such, Section 40 (2) of the FOIA applies along with the Trusts duty of confidentiality. Therefore under s.2 (3) (f) (ii) of the FOIA, there is an absolute exemption from disclosure on the grounds that it would contravene the First Data Protection Principle.

- The Trust has a duty under the Data Protection Act 2018 and specifically the First Data Protection Principle to ensure personal data regarding staff and patients is processed fairly and lawfully. Disclosure of such data which may identify an individual, either through the data alone or other data in conjunction with that data which may identify an individual would therefore breach this principle.

The Data Protection Act 2018 defines sensitive personal data to include data relating to the "physical or mental health or condition" of a person. Any such information about specific individuals falls within this category and disclosure of such data including statistical data, with any potential likelihood of identification would breach the Data Protection Act 2018.

Alder Hey Children's
NHS Foundation Trust

POLICY REF:
VENESECTION FOR IRON OVERLOAD IN PAEDIATRIC HAEMATOLOGY PATIENTS

Document Properties	
Version:	1
Name of Ratifying Committee:	<insert name of ratifying committee- may not be required for local documents >
Date Ratified:	<insert date ratified>
Name of Originator/Author:	[redacted]
Name of Approval Committee:	<insert name of approval committee>
Date Approved:	September 2022
Executive Sponsor:	<insert title of lead executive for policy- may not be required for local documents>
Date Issued:	<insert month and year>

respect excellence innovation together openness

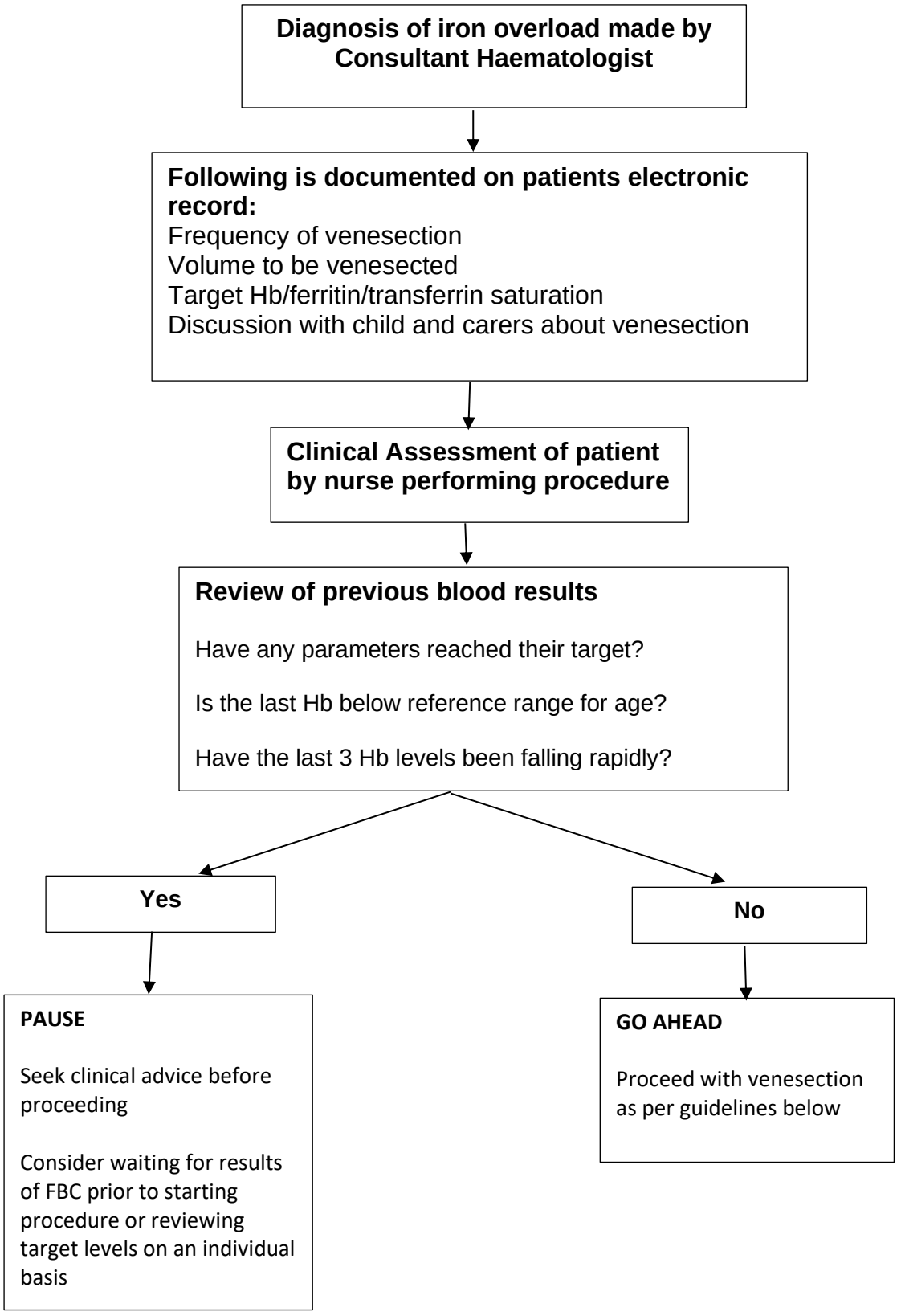
Review Date:	September 2025

1. Version Control, Review and Amendment Logs

Version Control Table				
Version	**Date**	**Author**	**Status**	**Comment**
1	24/08/22	[redacted]		

Record of changes made to POLICY TITLE – Version XX			
Section Number	**Page Number**	**Change/s made**	**Reason for change**

2. Quick Reference Guide – Venesection for iron overload in paediatric haematology patients



Contents

<The Contents Section above will update automatically in line with the section headings. To update, right click over the section above and click 'Update Field'>

3. Introduction

3.1 Iron overload can lead to multiple organ dysfunction/failure and poor quality of life in a variety of patients with different haematological conditions, including haemoglobinopathies, polycythaemias, haemochromatosis and post haematopoietic stem cell transplant. Patients entering into haematopoietic stem cell transplantation with iron overload have an increased risk of delayed engraftment, veno-occlusive disease (VOD), infection and GVHD.
In addition to oral or parenteral iron chelation, venesections may also be used as a treatment modality for the management of iron overload in selected patients. This SOP aims to define indications and contra-indications for the use of venesections in this clinical scenario, the competencies and equipment required, and to describe the procedures to be followed.

4. Definitions

VOD – veno-occlusive disease
GVHD – graft versus host disease
FBC – full blood count
LFT – liver function test
Hb – Haemoglobin
Hct - Haematocrit

5. Authorised Personal/Staff Competencies

Daycare medical staff and/or senior nurse
Venepuncture/Cannulation skills
Clinical assessment skills

6. Diagnosis of Iron Overload and its clinical significance

6.1 Whatever the aetiology, the diagnosis of iron overload and estimation of its clinical impact (ie: iron content in tissues, organ dysfunction) should include at least the following:

- FBC, blood film
- Ferritin, serum iron, transferrin, transferrin saturation,
- Renal and liver function

The following tests may be indicated in selected patients:

- Hepatitis B/C serology if evidence of liver dysfunction or liver iron loading
- Endocrine assessment if evidence of endocrine dysfunction. This may include Thyroid Function Testing, Growth Hormone Testing
- HFE genotype status if family history of or suspicious of Hereditary Haemochromatosis – see guidelines from BSG and BSH for reference "Diagnosis and therapy of genetic haemochromatosis (review and 2017 update) (bsg.org.uk)"
- Ferriscan/T2* of the heart/liver for estimation of iron content

6.2 **Indications for treatment**

Consider intervention/treatment for the following patients:

- Serum ferritin > 1000 microg/L
- Transferrin Saturation > 50%
- Estimated liver iron > 5 mg/g dry weight by MRI
- Cardiac T2* MRI < 20 msec
- Any sign of iron-related dysfunction of target organs (liver, heart, hypophysis, thyroid, pancreas). In these cases, biopsy of the relevant organ to correlate dysfunction with iron overload may be necessary

6.3 **Patients can be offered venesection if:**

- They have documented iron overload needing treatment, as above
- Hb is within normal limits
- Cardiovascularly stable with no contraindication to venesection
- Borderline Hb levels are not an absolute contraindication if venesections are needed and still thought to be the most clinically appropriate treatment modality for controlling the iron overload. Essential to discuss with haematology team, consideration should be given to the concurrent use of erythropoietin to support Hb
- (Verbal) patient/parent consent to procedure available

7. Venesection Procedure

Venesection involves the removal of a specified amount of blood by venepuncture to control iron overload. Frequency as well as ferritin or liver iron targets will be directed by the haematology team, but venesection will typically occur every 3 to 4 weeks if tolerated. It should only be performed in the afternoon, after lunch in a well hydrated patient.

The procedure should only be undertaken by qualified members of staff who have been assessed and are competent in venepuncture and cannulation skills.

- A clearly documented plan from the child's consultant should be on patients electronic record
- Prior to each venesection procedure the following should be done, as a baseline:
    - Weight, baseline temperature, pulse, respirations and blood pressure.
    - Make a brief clinical assessment of the patient including any new or change to medical conditions, Ensure patient is well clinically and that there are no active clinical issues of concern.
    - Send FBC, U&Es, LFT's, ferritin, iron studies (to include transferrin and transferrin saturation).
- Ensure that the patient is fully informed of the procedure and any questions are answered.
- If there is a history of fainting at time of venepuncture - lie flat for procedure and 30 minutes after completion.
- The nurse must always ensure that the patient is feeling well and that he/she has eaten as hunger/dehydration can lead to fainting during or post procedure.
- The patient's previous Hb/ferritin/iron study results must be checked and reviewed prior to carrying out procedure to ensure they are not anaemic/becoming anaemic or have reached target values. If there is concern regarding anaemia then await FBC on day of procedure before proceeding.
- The amount of blood to be venesected must be calculated and documented prior to each venesection based on the patient's weight (5-7mls/kg to max 350mls). Some patients only tolerate a lower venesection amount so this can be lower if clinically appropriate.
- Patient is cannulated and venesected over 30 mins or slower.
- First blood specimen removed is used for laboratory tests.
- Patient should be allowed to sit up after procedure and have a sugary drink (parents are asked to bring a sweet drink at each visit). If required 5-10ml/kg of normal saline can be administered.
- After 15-30 minutes patient may be discharged if well.
- Precautions explained to child/parent prior to each discharge:
    - Keep activity to a minimum on same day (e.g. no active sports) especially if returning to school
    - If feeling faint (cold, clammy) within few hours after venesection:
        sit down and put head between knees or lie flat
        have a sweet drink if possible
        stay sitting/lying until feeling better
        slowly get back onto feet
- Inform CNS of fainting episode or unwell after discharge.
- Amount of blood venesected, any complications, patient tolerance should be documented on the patient's medical record.

8. Monitoring

The approval / ratification committees have ongoing responsibility to agree the monitoring arrangements for the policy. This may be assured via the committee reporting schedule or other agreed mechanism.

Include details of the monitoring that will be carried out (eg audit of process, review of incidents etc), who is responsible for ensuring that this monitoring is completed and how often. Also include how the monitoring will be reported to provide appropriate assurance.

Monitoring	Lead Responsible	Frequency	Responsible Committee
Review of incidents	[redacted]	12 monthly	
Compliance with guideline		12 monthly	

9. Further Information

https://www.haemochromatosis.org.uk/

RCN – Venesection best practice guideline 2020

10. Checklist for Approval of Policies

		Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear that the document is a Trust policy?	Yes	
2.	**Rationale**		
	Are reasons for development of the policy stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are individuals involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?		Sent to 3B for comments
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	

		Yes/No/ Unsure	Comments
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?		
	Are local/organisational supporting documents referenced?	N/A	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate, have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	Yes	Circulate to professionals undertaking the procedure
	Does the plan include the necessary training/support to ensure compliance?	Yes	
8.	**Document Control**		
	Does the document include version history and identify key changes since the last approved version?	Yes	New policy
9.	**Process for Monitoring Compliance**		
	Are there measurable standards or KPIs to support monitoring compliance of the document?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so, is it acceptable (Default is 3 years)?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?	Yes	

The policy author is responsible for completing the above checklist prior to submission for approval.

11. Equality Impact Assessment

Initial Equality Impact Assessment (EIA) Form	
This section must be completed at the development stage i.e. before approval or ratification. For further guidance please refer to the Equality Impact Assessment (EIA) Policy on DMS.	
Part 1	
Name and Job Title of Responsible Person(s): Click or tap here to enter text.	**Contact Number:** Click or tap here to enter text.
Department(s): Click or tap here to enter text.	**Date of Assessment**: Click or tap to enter a date.
Name of the policy / procedure being assessed: Click or tap here to enter text.	
Is the policy new or existing? New ☐ Existing ☐	
Who will be affected by the policy (*please tick all that apply*)? Staff ☐ Patients ☐ Visitors ☐ Public ☐	
How will these groups / key stakeholders be consulted with? Click or tap here to enter text.	
What is the main purpose of the policy? Click or tap here to enter text.	
What are the benefits of the policy and how will these be measured? Click or tap here to enter text.	
Is the policy associated with any other policies, procedures, guidelines, projects or services? Yes ☐ No ☐ *If yes, please give brief details:* Click or tap here to enter text.	
What is the potential for discrimination or disproportionate treatment of any of the protected characteristics? *Please use the **Equality Relevance** guidance (see on DMS) to specify who would be affected (e.g. patients with a hearing impairment, staff aged over 50).* *Please tick either positive, negative or no impact then explain in reasons and include any mitigation e.g. requiring applicants to apply for jobs online would be negative as there is potential disadvantage to individuals with learning difficulties or older people (detail this in the reason column with evidence) however applicants can ask for an offline application as an alternative (detail this in the mitigation column)*	

Protected Characteristic	Tick either positive, negative or no impact			Reasons to support your decision and evidence sought	Mitigation / adjustments already put in place
	Positive Impact *(benefit)*	**Negative *(disadvantage or potential disadvantage)***	**No Impact**		
Age	☐	☐	☐		
Sex	☐	☐	☐		
Race	☐	☐	☐		
Religion or belief	☐	☐	☐		
Disability	☐	☐	☐		
Sexual orientation	☐	☐	☐		
Pregnancy and maternity	☐	☐	☐		
Gender reassignment	☐	☐	☐		
Marriage and civil partnership	☐	☐	☐		
Other (specify)	☐	☐	☐		
If you have identified no negative impact for all please explain how you reached that decision and provide reference to any evidence (e.g. reviews undertaken, surveys, feedback, patient data etc.) Click or tap here to enter text.					
Does the policy raise any issues in relation to Human Rights as set out in the Human Rights Act 1998? Yes ☐ No ☐ *See **Equality Relevance** guidance (on DMS) for more details (NB if an absolute right is removed or affected the policy will need to be changed. If a limited or qualified right is removed or affected the decision needs to be proportional and legal)*					

If you have identified negative impact for any of the above characteristics, and have not been able to identify any mitigation, you MUST complete a Full Equality Impact Assessment. Please speak to the Head of Equality, Diversity and Inclusion and see the Full Equality Impact Assessment (EIA) Form on DMS			
Action	**Lead**	**Timescale**	**Review Date**
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.

Declaration	
I am satisfied this document / activity has been satisfactorily equality impact assessed and the outcome is:	Tick one box
Continue – EIA has not identified any potential for discrimination/adverse impact, or where it has this can be mitigated & all opportunities to promote equality have been taken	☐
Justify and continue – EIA has identified an adverse impact but it is felt the policy cannot be amended. ***You must complete a Full Equality Impact Assessment (EIA) Form before this policy can be ratified***.	☐
Make Changes – EIA has identified a need to amend the policy in order to remove barriers or to better promote equality ***You must ensure the policy has been amended before it can be ratified.***	☐
Stop – EIA has shown actual or potential unlawful discrimination and the policy has been removed	☐
Name: Click or tap here to enter text.	Date: Click or tap to enter a date.

Approval & Ratification		
Policy Author:	Name: Click here to enter text.	Job title: Click here to enter text.
Approval Committee:	Click here to enter text.	Date approved: Click here to enter a date.
Ratification Committee:	Click here to enter text.	Date ratified: Click here to enter a date.
Person to Review Equality Analysis:	Name: Click here to enter text.	Review Date: Click here to enter a date.

Comments:	Click here to enter text.