Preparation for Autologous Stem Cell Harvest and Transplant

NHS University Hospitals of Leicester NHS Trust

Trust Ref:E3/2024

Introduction and Who this Standard Operating Procedure applies to

This CYPICS network guideline has been developed by clinicians from Nottingham Children's Oncology Unit with consultation across the network including from the Leicester Royal Infirmary and has been ratified by the Leicester Children's Hospital guideline process.

This guideline applies to all children and young people under the age of 19 years who are receiving chemotherapy for malignant disease

UHL local Paediatric Oncology specialists are:

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NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST & UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

Preparation for Autologous Stem Cell Harvest and Transplant

CHILDREN'S HOSPITAL SOP

East Midlands Children's and Young Persons' Integrated Cancer Service Post-Autologous Stem Cell Transplant Programme

Title	3236 - Preparation for Autologous Stem Cell Harvest and Transplant
Author	Elizabeth Ralling – Quality Manager (Katie Manning – Previous Quality Manager)
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Version	2
Summary of Changes from Previous Version	4.5 change length of time irradiated and HEV negative products must be used from the initiation of conditioning chemo/radiotherapy (at SCFT) until 6 months post-transplant. 4.4 and 5.2 NUHNT.cypicsasct@nhs.net will be copied into emails from SCFT regarding HSCT/Form/007 mobilisation and harvest checklist for autologous stem cell transplant Addition of appendix 1 Alteration of some wording to ensure applicability across NUH and UHL. Some minor wording changes for clarity.

Consultation Undertaken	Clinical and Collection Quality Managers Sheffield Children's NHS Foundation Trust (SCFT). Dr Dan Yeomanson, SCFT Consultant Oncologist. Kathryn Edwards, SCFT BMT CNS. Dr Sophie Wilne, Transplant Programme Director. NUH Consultant Paediatric Oncologists, UHL Consultant Paediatric Oncologists. Margaret Parr, Lead Nurse, Oncology Liaison Nurses.
Accreditation Implications	Supports compliance with FACT-JACIE standards
Target Audience	EMCYPICS clinical team.
Lead Manager	Dr Sophie Wilne
Authorised by: (Programme Director or Quality Manager)	Name: Sophie Wilne Signature: **SIGNED ON MASTER COPY** Role: Programme Director Date:

SOP Number & Full Title:	**3236 - Preparation for Autologous Stem Cell Harvest and Transplant**
Author ***(include email and role):***	Elizabeth Ralling, CYPICS Quality Manager Elizabeth.ralling@nuh.nhs.uk
Division & Specialty	Family Health, Children and Young People's Integrated Cancer Service
Version	2
Ratified by	Dr. Sophie Wilne, Autologous Stem Cell Transplant Programme Director
Consultation:	Clinical and Collection Quality Managers, Sheffield Children's Foundation Trust (SCFT); Dr. Dan Yeomanson, SCFT Consultant Oncologist; Kathryn Edwards, SCFT Bone Marrow Transplant Nurse Specialist; Dr. Sophie Wilne, Transplant Programme Director; UHL Consultant Oncologists; Margaret Parr, CYPICS Lead Nurse; Oncology Liaison Nurses.
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Audience	East Midland Children and Young People's Integrated Cancer Service (CYPICS) Clinical team

Document Control

Document Amendment Record

Version	Issue Date	Author

V1	December 2020	Katie Manning
V2	September 2023	Elizabeth Ralling

Contents

1. Introduction

1.1 Patients under the care of the East Midlands Children's and Young Persons' Integrated Cancer Service (EMCYPICS) may be identified as eligible for an autologous haematopoietic stem cell transplant (HSCT) under the clinical commissioning indication list.

1.2 The EMCYPICS autologous transplant programme is provided in collaboration with Sheffield Children's NHS Foundation Trust (SCFT). Patients are referred to SCFT for assessment and consent prior to collection of stem cells. The patient's named consultant will decide a suitable timeframe for transplant in collaboration with the SCFT haemopoietic stem cell transplant (HSCT) team. Patients will then return to SCFT for their conditioning treatment and autologous SCT after a suitable therapeutic interval. This is not a simple, automatic sequential procedure as the patient will be required to meet criteria for transplant following re-assessment of their disease and clinical status.

1.3 There will be provision for some patients to undergo stem cell collection when reinfusion of the stem cells is not in their current treatment plan (rainy days). In this circumstance, there will not be automatic progression from 'preparation for stem cell harvest or transplant' to 'preparation for high dose therapy and autologous SCT'.

2. Purpose and Objectives

2.1 The purpose of this SOP is to outline the process that should be followed for patient identification and referral for autologous SCT.

2.2 Timely and effective communication within CYPICS MDT's will facilitate early identification of patients eligible for autologous SCT. Referral for autologous SCT can then be completed and sent to the SCFT HSCT team to enable transplant planning and communication with patients and their families.

2.3 Medical and nursing staff working within EMCYPICS will be aware of their responsibilities to facilitate safe and comprehensive care throughout the patient pathway for autologous SCT.

2.4 Clear, standardised guidance for all staff, including the NUH Quality Manager, administrative and clinical teams in both NUH and UHL, will ensure that the associated contributory tasks are completed to facilitate the patient's stem cell journey.

3. Responsibilities

3.1 The patient's named consultant (or nominated deputy in their absence) is responsible for ensuring the patient is discussed at the appropriate MDT at diagnosis and key treatment or reassessment time points.

3.2 The relevant MDT (+/- the appropriate national disease panel) is responsible for identifying patients who may be eligible for autologous SCT under the current clinical commissioning indication lists. The relevant MDT will decide whether the patient is fit to progress to autologous SCT at the appropriate treatment time point.

3.3 The EMCYPICS Quality Manager is responsible for commencing form ASCT/Form1/C/002 Pre-Autologous Stem Cell Harvest Checklist following MDT decision to harvest and then ensuring the form is completed and added to the patient's electronic medical record.

3.4 The patient's named consultant is responsible for ensuring completion of the SCFT autologous SCT referral form ASCT/SCFT/HSCT/Form/008 = HSCT Form 008 External PBSC Referral Form. This must be emailed securely to the SCFT HSCT team and EMCYPICS Quality Manager within 7 days of MDT decision.

3.5 The liaison nurses, nursing or medical teams are responsible for undertaking or requesting relevant pre-autologous SCT investigations as requested by SCFT or the EMCYPICS clinical teams.

3.6 The EMCYPICS Quality Manager is responsible for ensuring the completion of ASCT/Form2/C/002 Pre-admission Checklist for Autologous Stem Cell Transplant. The Quality Manager will ensure that the SCFT HSCT team receive pdf copies of formal pre-transplant investigations including but not limited to GFR and echocardiogram within 7 days of tests. The Quality Manager will ensure that ASCT/Form2/C/002 is added to the patient's medical record upon completion.

3.7 The EMCYPICS Quality Manager is responsible for ensuring relevant MDT outcome summaries are sent, via secure email, to the SCFT HSCT team within 14 days of a request.

4. Procedure

4.1 Patient Selection

Patients will be discussed at the relevant MDT at diagnosis and at key treatment time points or as clinical condition requires. Patients may be identified as being eligible for an autologous SCT under current clinical commissioning indication lists.

Factors affecting this decision will depend upon patient's disease status, response to previous treatment and patient's fitness for high dose chemotherapy. Following the

MDT decision to proceed to autologous stem cell harvest the EMCYPICS Quality Manager will commence ASCT/Form1/C/002 Pre-autologous stem cell harvest checklist.

4.2 Referral

The patient's named consultant must complete the electronic referral form ASCT/SCFT/HSCT/Form/008 = HSCT Form 008 External PBSC Referral Form and email securely to the SCFT transplant team via haematology.sch@nhs.net and the EMCYPICS Quality Manager within 7 days of MDT decision. A copy of this referral form should be added to the patient's medical record.

HSCT Form 008 External PBSC Referral Form is an SCFT document. An up to date blank copy can be located within the Paediatric Oncology shared drive. (Paediatric Oncology\JACIE\Forms\ACTIVE\SCFT forms).

Formal acceptance of the referral will be received at the next SCFT/NUH Quality Management Group meeting. This acceptance will be recorded in the meeting minutes, which will be uploaded to patient records. A note will also be made in the patient's Pre-Autologous Stem Cell Harvest checklist (ASCT/Form1/C/002), which will also be uploaded to electronic patient records.

4.3 Consent

Consent for stem cell harvest/transplant is not obtained at NUH or UHL. Patients are transferred to SCFT under NHS inter-provider transfer arrangements for assessment prior to stem cell procedures. The initial consultations include arrangements for informed consent as required by HTA licensing regulations.

4.4 Preparation for autologous stem cell harvest or transplant

The patient's named consultant will receive the planned mobilisation date from the SCFT HSCT team.

The named consultant (or nominated deputy in their absence) must liaise with the paediatric surgical team to organise Vascath insertion in preparation for stem cell harvest.

The patient's named consultant and liaison nurses will receive ASCT/SCFT/HSCT/Form/007 = HSCT/Form/007 mobilisation and harvest checklist for autologous stem cell transplant from the SCFT HSCT team. This will advise required investigations, mobilisation start date and GCSF dosing. This form is sent to the group email NUHNT.paediatriconcology@nhs.net and the liaison nurses check this email not less than once a week. NUHNT.cypicsasct@nhs.net Treating team at UHL will also be copied in as appropriate.

These investigations may include mandatory virology blood tests for which written consent must be obtained within 30 days of collection using NHS Blood and Transplant consent form 2B 'Consent for the Testing, Storage and Discard of stem cells or lymphocytes.' Instructions for virology testing can be found in SCFT HSCT/065 app 1 'Virology Testing for bone marrow harvest by referring centres'.

Medical staff must complete the request for irradiated blood and blood components as per ASCT/C/018 Transfusion Support for children and young people with malignancy and bone marrow failure. Irradiated products must be used for the 7 days prior to harvest.

All data required for HSCT/Form/007 mobilisation and harvest checklist for autologous stem cell transplant must be completed and required investigations undertaken. This includes a pregnancy test for all females >11 years of age and those < 11 years of age who have commenced menarche prior to starting GCSF.

The required GCSF must be prescribed and administered according to the HSCT/Form/007 mobilisation and harvest checklist.

A full blood count must be obtained as a baseline prior to starting GCSF.

The patient's haemoglobin should be between 115-125g/l and the patient should have a platelet count >25x10^9/l prior to collection. Transfusion with irradiated products should be completed, to maintain these levels, prior to admission to SCFT as per ASCT/C/018 Transfusion Support for children and young people with malignancy and bone marrow failure.

The EMCYPICS Quality Manager will ensure that all required information is documented in ASCT/Form1/C/002 prior to stem cell harvest and that the completed form is added to the patient's medical record.

4.5 Preparation for high dose therapy and autologous SCT

The decision to proceed to high dose therapy and autologous SCT will be made at the relevant MDT and documented within the MDT Outcome Summary. The quality manager will commence ASCT/Form2/C/002 Pre-admission Checklist for Autologous Stem Cell Transplant following MDT decision. The date of admission to SCFT for high dose therapy and autologous SCT is organised by SCFT in collaboration with the patient's named consultant within EMCYPICS.

The patient's named consultant will receive a list of required pre-transplant investigations from the HSCT team at SCFT. The liaison nurses and medical team will organise the required investigations and ensure these are completed a minimum of 7 days prior to the transplant admission date. PDF copies of formal pre-transplant investigations including but not limited to GFR and echocardiogram will be sent to the HSCT team at SCFT within 7 days. This will be documented within form ASCT/Form2/C/002.

Medical staff must complete the request for irradiated blood and blood components as per ASCT/C/018 Transfusion Support for children and young people with malignancy and bone marrow failure. Irradiated products must be used from the initiation of conditioning chemo/radiotherapy (at SCFT) until 6 months post-transplant.

The quality manager will ensure that ASCT/Form2/C/002 is completed and added to the patient's medical record.

EMCYPICS patients will be transferred from SCFT to NUH on the day following infusion of autologous stem cells (D+1), or as soon as clinically stable thereafter, as per ASCT/C/006 Preparation for patient transfer to NUH post high dose therapy and autologous stem cell transplant.

5. Limitations

5.1 Patients will be excluded from stem cell mobilisation or collection if:

5.1.1 Their performance status is considered to be too low for them to be suitable for a high dose therapy procedure.

5.1.2 Renal failure is not a contra-indication to stem cell harvesting but the doses of mobilising chemotherapy may have to be adjusted or mobilise with GCSF alone.

5.2 In the case of limited ability or inability to access the shared email NUHNT.paediatriconcology@nhs.net to retrieve HSCT/Form/007 mobilisation and harvest checklist for autologous stem cell transplant, please note that NUHNT.cypicsasct@nhs.net should have been copied into email, accessible by the NUH QM. Alternatively, staff on Ward E39/E39 daycare can obtain access to the information outlined in this form by contacting the patient's named consultant. For patients treated at UHL treating consultant and Liaison nurse will receive the information.

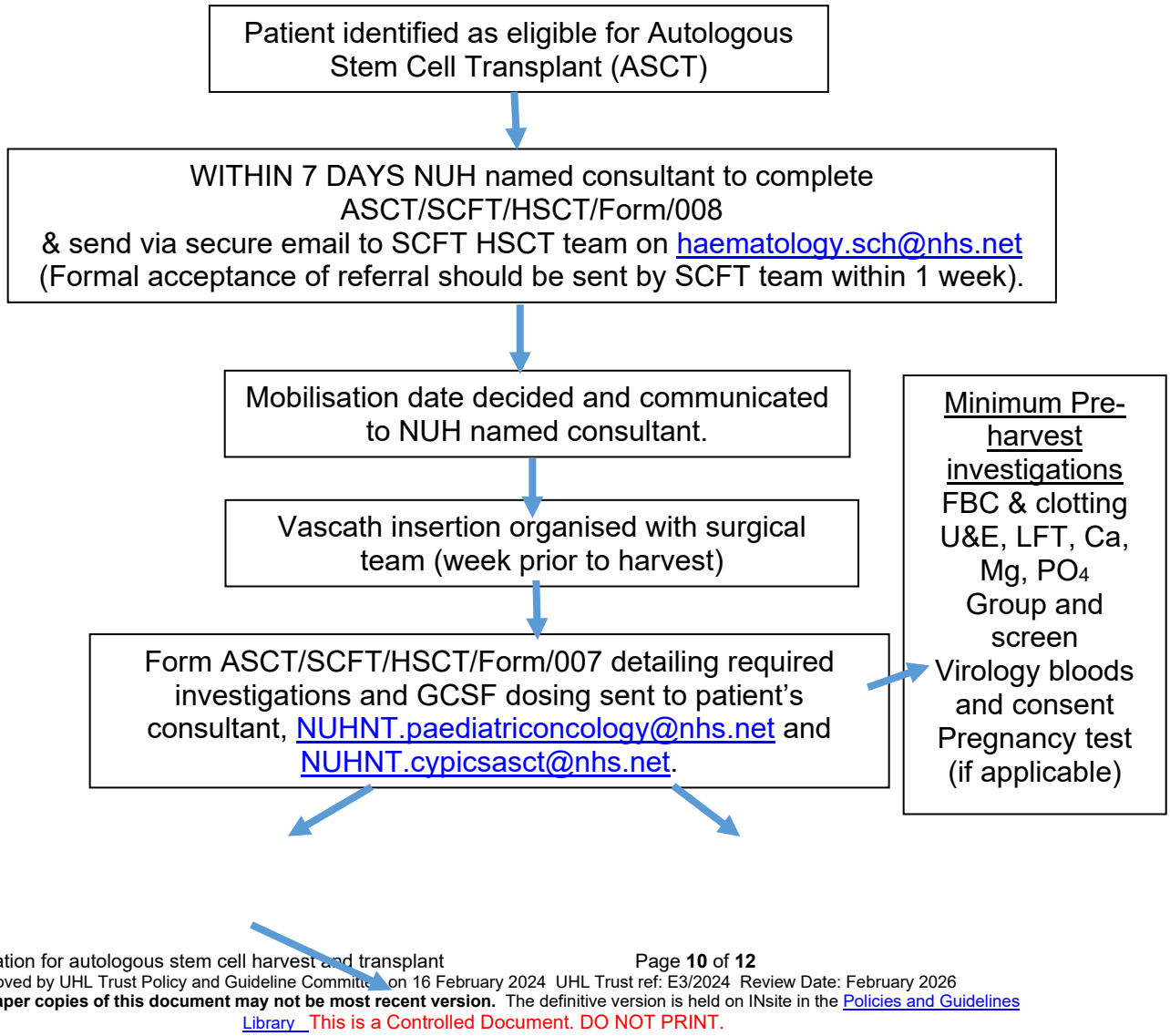
5.3 In the case of a prolonged absence of the quality manager, which would impact on the responsibilities within section 3, refer to the Autologous Stem Cell Transplant Programme Recovery Plan for cover arrangements.

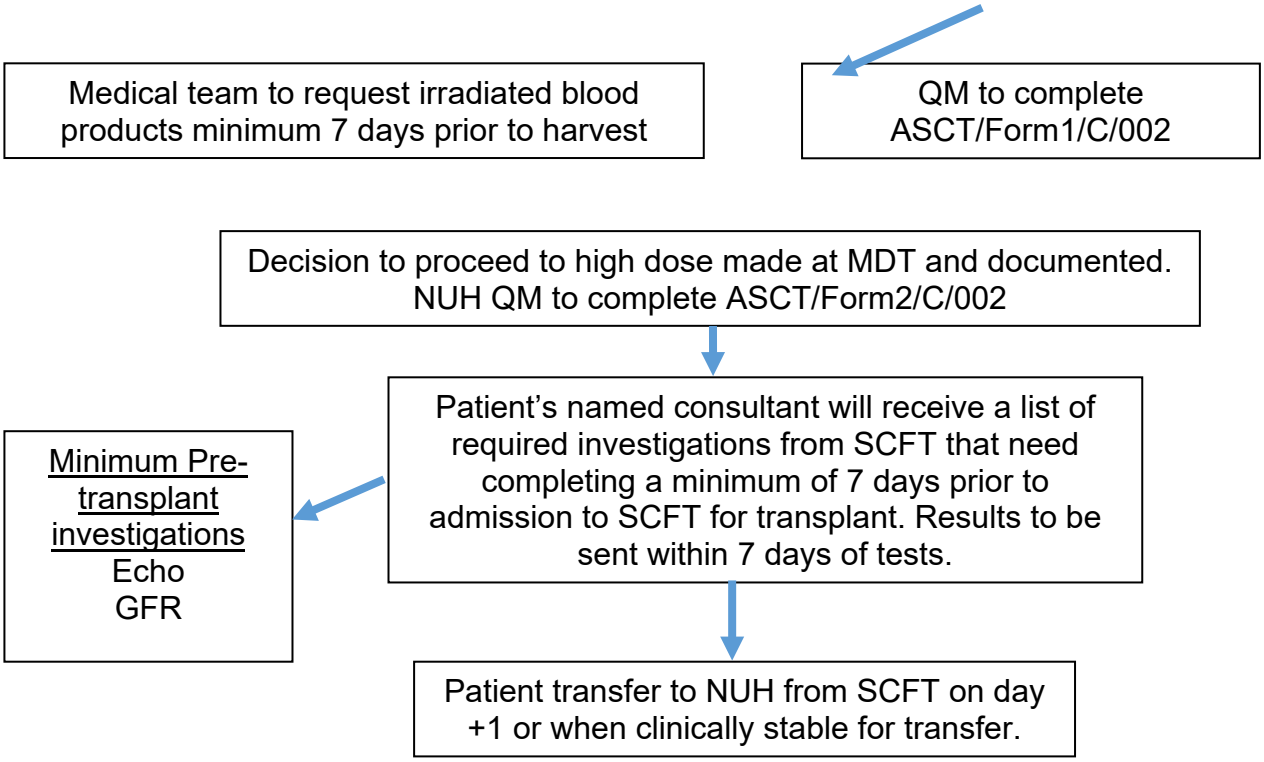
These instructions should be followed and planned deviations must be documented in the patient notes and authorised by the Programme Director. Unplanned deviations must be reported according to Incident Management SOP ASCT/Q/003 (pending).

6. References/Further Information

Sheffield Children's Hospital NHS Foundation Trust and Nottingham University Hospitals NHS Trust Agreement for the assurance and governance of JACIE standards as required by Sheffield Children's NHS Foundation Trust as an accredited centre.

Appendix 1: Flow chart for the preparation for stem cell harvest and transplant





UHL Education and Training

None

Key Words

East Midlands Children's and Young Persons' Integrated Cancer Service (EMCYPICS), Haematopoietic stem cell transplant (HSCT)

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

CONTACT AND REVIEW DETAILS	
SOP Lead (Name and Title) Emma Ross; Consultant Paediatric Oncologist	**Executive Lead** **Medical Director**
Details of Changes made during review: **New document for UHL** **Changes made listed page 2**	