

The Oxford Blood and Marrow Transplant/Immune Effector Cell Programme

Oxford University Hospitals NHS Foundation Trust

Department of Clinical Haematology

Quality Manual
June 2023

Description and aims

To provide details of the structure, management and organisation the the Oxford Blood and Marrow Transplant (OxBMT) and Advanced Cellulat Therapies (ACT) Programme, including autologous satellite service at Buckinghamshire Healthcare NHS Trust and Royal Berkshire NHS Foundation Trust

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Abbreviations

ACT	Advanced Cellular Therapies
ACU	Ambulatory Care Unit
AT(I)MP	Advanced Therapy (Investigational) Medicinal Products
ATMP	<p>An advanced therapy medicinal product (ATMP) is a medicinal product which is either:</p> <ul style="list-style-type: none"> • a gene therapy medicinal product • a somatic cell therapy medicinal product • a tissue engineered product
BMT	Blood and Marrow Transplant
BHT	Buckinghamshire Healthcare NHS Trust
BMT/IECQM	Blood and Marrow Transplant/Immune Effector Cell Quality Meeting
CAR	Chimeric antigen receptors (CARs, also known as chimeric immunoreceptors, chimeric T cell receptors or artificial T cell receptors) are engineered receptors that combine a new specificity with an immune cell to target cancer cells
CAR-T	Chimeric antigen receptors T cells
DL	Donor Lymphocyte
DTU	Day Treatment Unit (OUH)
FACT	Foundation for the Accreditation of Cellular Therapy
IEC	Immune Effector Cell
HTA	Human Tissue Authority
JACIE	Joint Accreditation Committee for the ISCT and EBMT
MOG	Monthly Operational Government meeting
NHS	National Health Service
NHSBT	National Health Service Blood and Transplant
NSSG	Network Site Specific Group (Haematology)
OUH NHS Trust	Oxford University Hospitals National Health Service Foundation Trust
OxBMT	Oxford Blood and Marrow Transplant
PBSC	Peripheral Blood Stem Cells
QM	Quality Manager
QMP	Quality Management Plan
RBT	Royal Berkshire NHS Foundation Trust
SCI	Stem Cell and Immunotherapies Service (NHSBT)
SIRI	Serious Incident Requiring Investigation

SLA	Service Level Agreement
TAS	Therapeutic Apheresis Service (NHSBT)
T cell	A T cell, or T lymphocyte, is a type of lymphocyte (a subtype of white blood cell) that plays a central role in cell-mediated immunity. T cells can be distinguished from other lymphocytes, such as B cells and natural killer cells, by the presence of a T-cell receptor on the cell surface.
TCR	T-cell receptor
TPA	Third Party Agreement
TVSCN	Thames Valley Strategic Clinical Network

1. Purpose

The purpose of the Quality Manual is to outline and define the Quality Management Plan (QMP), responsibilities and tasks necessary to meet donor, patient and service requirements; and to verify that those requirements have been met.

The overarching title, Oxford Blood and Marrow Transplant (OxBMT) and Advanced Cellular Therapies (ACT) Programme, incorporates; allogeneic and autologous transplantation, Advanced Cellular Therapies (ACT) including Chimeric Antigen Receptor T (CAR-T) cell therapy, peripheral blood stem cell (PBSC) and donor lymphocyte (DL) collection, bone marrow (BM), cord blood (CB) and DL processing service in Oxford, and the satellite autologous transplant units at Buckinghamshire Healthcare NHS Trust (BHT), and the Royal Berkshire NHS Foundation Trust (RBT).

The Quality Management Plan (QMP) ensures that the Oxford Blood and Marrow Transplant/Advanced Cellular Therapies (OxBMT/ACT) Programme conforms to the standards and content of:

- a) FACT-JACIE International standards for cellular therapy product collection, processing and administration, 7th Edition
- b) Human Tissue Authority, directions under the Human Tissue Act, 2004:
- c) Human Tissue Authority, Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment (April 2018)
- d) EU Tissue and Cells Directive 2004/23/EC, and supporting Commissioning Directives 2006/17/EC and 2006/86/EC
- e) DOH Cancer Service Standards Haematology Measures (2013)
- f) DOH Cancer Service Standards Chemotherapy Measures (2011)
- g) DOH Cancer Service Standards Acute Oncology Measures (2011)
- h) NICE Haematological cancers:improving outcomes (2016)
- i) BCSH Facilities for the treatment of adults with haematological malignancies – 'Levels of Care': Haemato-Oncology Task Force 2009, published 2016.

And other relevant regulations, standards, and guidance

This quality manual should be read in conjunction with the following documents: Quality File for OxBMT/ACT; National Health Service Blood and Transplant (NHSBT) Site Master File and Quality Management Plan, therapeutic Apheresis Service (TAS) Oxford, and Quality Manual for Stem Cell and Immunotherapies Service (SCI), Local Addendum located within the Quality file.

2. Format

Policies/procedures outlined within the text are referenced by their OxBMT, ACTCAR-T, Clinical Haematology, NHSBT, Oxford University Hospitals (OUH) NHS Foundation Trust or the Thames Valley Clinical Strategic Network (TVCSN), Buckinghamshire Healthcare NHS Trust (BHT), Royal Berkshire NHS Foundation Trust (RBT), Network Site Specific Group (NSSG) document name and reference.

OxBMT/ACT and OUH Clinical Haematology policies, procedures, guidelines, and associated documents referred to are controlled by the OUH Clinical Haematology Quality Manager. OUH, BHT, and RBT NHS Trusts and TVSN NSSG documents are managed through local processes. NHSBT documents have a national management system. The protocols used at the RBT and BHT NHS Trust satellite units are common unless specified. All documents contain version numbers and effective dates, along with revision details and authorisation. Documents referenced within other

documents are referenced by document name, number and source but not the version number to ensure document reference remains current even if version number changes have occurred.

3. Service Profile

OxBMT/ACT

OxBMT/ACT programme is based within the OUH Department of Clinical Haematology in the Cancer and Haematology Centre at the Churchill Hospital.

There are two autologous satellite units; one managed by Buckinghamshire Healthcare NHS Trust at Stoke Mandeville Hospital, Aylesbury and one managed by Royal Berkshire NHS Foundation Trust at the Royal Berkshire Hospital, Reading. These hospitals are located 20 and 27 miles, respectively, (40minute drive) from the Churchill Hospital, Oxford

The Oxford Department of Clinical Haematology provides a general clinical haematology service to the local area, with specialist and Blood and Marrow Transplant (BMT) and Advanced Cellular Therapies (ACT) services to the Thames Valley.

OxBMT provides:

A transplant programme: Following high dose therapy, transplant procedures include autologous stem cell rescue, allogeneic haematopoietic stem cell transplantation using HLA-matched sibling donors, unrelated donors, haploidentical related donors, or unrelated umbilical cord blood. Haematopoietic stem cell sources include bone marrow (BM), peripheral blood stem cells (PBSC) or cord blood (CB). Donor lymphocyte infusions (DLI) may also feature for some patients.

ACT provides:

The Oxford ACT programme provides a regional (Thames Valley) service for the referral, assessment and selection of patients for ACT therapies; collection and delivery of autologous cells for the manufacture of ACT; receipt, delivery and administration of ACT to patients; monitoring for ACT related complications (e.g. CRS/ICANS); long term patient follow up and data reporting for ACT patients.

The combined programme involves the work of medical, nursing, clerical, managerial, pharmacy, dietetic, allied health professional, pastoral, social, psycho-social support staff, together with services from the National Health Service Blood and Transplant (NHSBT) Oxford Therapeutic Apheresis Service (TAS) and Stem Cell and Immunotherapies Service (SCI), donor registries, laboratories, radiotherapy and advanced therapy medicinal product (ATMP) facilities.

NHSBT, TAS and SCI Service hold service level agreements with the OUH/OxBMT/ACT, BHT, and RBT for the provision of services as described below.

Haemopoietic stem cells are routinely harvested from three sources: bone marrow, peripheral blood in which stem cells have been mobilised using cytokines, and neonatal umbilical cord blood (CB). In addition, donor and patient derived lymphocyte are collected from peripheral blood. Collections undertaken in Oxford are harvested in the TAS department at NHSBT, John Radcliffe Hospital, Oxford, on the Clinical Haematology Ward, Ambulatory Care Unit or Day Treatment Unit (DTU) at the Churchill Hospital, by the TAS team. BM and CB collections are carried out at other national and international donor collection facilities. Patients having transplants at BHT and RBT also have stem cell collection performed in the TAS department at NHSBT, Oxford. TAS, although managed separately by NHSBT, is fundamental and integral to the OxBMT/ACT programme. TAS provides an extracorporeal photopheresis (ECP) service and collection service for peripheral blood stem cell (PBSC) products, including donor and patient derived lymphocytes. It also harvests from unrelated donors for the British Bone Marrow Registry (BBMR) and Anthony Nolan. This service has a stand

alone JACIE, HTA and MHRA accreditation. TAS provides an independent consultant who oversees the review, assessment, and consent of related donors in line with JACIE and HTA recommendations.

SCI test, process, store and distribute products that are harvested locally as well as those received from other collection centres and registries, both nationally and internationally. All donations are processed in sterile conditions and then delivered to the clinical area, cryopreserved for later use, or sent to an ATMP facility for processing, as instructed on the prescription supplied by the clinician caring for the patient. The SCI are a JACIE accredited and HTA licensed service.

There is much joint working between the NHSBT services and OxBMT/ACT, both for common pathway development and supporting of individual structures; elements include quality manual, policy and procedure development, sharing of JACIE feedback and information. Each service attends the other's quality and/or monthly operational governance (MOG) meetings.

Joint working also takes places at a research and development level, OUH working with NHSBT and to manage a fully integrated research programme.

The NHSBT employs its own national quality management system to ensure the quality of the product and service. All adverse events in NHSBT are reviewed with the OxBMT/ACT team at the TAS Clinical Governance meetings, attended by the OxBMT/ACT quality manager and reviewed by the BMT and ACT Clinical Lead and the Programme Director. The OxBMT/ACT programme adverse events are reviewed with NHSBT staff at the OxBMT and ACT quality or MOG meetings. Each service retains copies of the minutes.

OxBMT/ACT Service details

Programme Director and Clinical Lead for BMT: Dr Andy Peniket

Administration address:
Haematology Secretariat
Level 2, Cancer Administration
Cancer and Haematology Centre
Churchill Hospital
Old Road
Oxford
OX3 7LJ

Telephone:
Secretary: 01865 235259 (During office hours)
Haematology Ward: 01865 235049 (Out of hours)

Clinical Lead for ACT: Dr Katerine Panopoulou

Administration address:
Haematology Secretariat
Level 2, Cancer Administration
Cancer and Haematology Centre
Churchill Hospital
Old Road
Oxford
OX3 7LJ

Telephone:

Secretary: 01865 235259 (During office hours)
Haematology Ward: 01865 235049 (Out of hours)

NHSBT TAS Oxford Service details

Collection Facility Director/Medical Director: Dr Rachel Pawson
Independent Related Donor Assessor: Dr Rachel Pawson

Address:

NHSBT Oxford Centre – Donor Centre
Level 2, John Radcliffe Hospital
Headley Way
Oxford
OX3 9BQ

Telephone:

Office: 01865 220303 (Office hours)
On Call: 0300 020 0496 (Out of hours)

NHSBT SCI Oxford Service details

Medical Director: Dr Rachel Pawson
Head Laboratory Director: Dr Gurman Kaur.
Deputy Head Laboratory Director: Steve Bowen

Address:

As for NHSBT TAS Oxford

Telephone:

Laboratory: 01865 387949 (Office hours)
On Call: 07764280663 (Out of hours)

BHT Service details

Lead Clinician: Dr Robin Aitchison

Address:

Cancer Care and Haematology Unit
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
Bucks
HP21 8AL

Telephone:

Unit: 01296 316053 (Office hours)
Haematology Ward: 01296 316336 (Out of hours)

RBT Service details

Lead Clinician: Dr Asif Khan

Address:
Haematology Department
Royal Berkshire Hospital
London Rd
Reading
RG1 5AN

Telephone: 0118 322 8145
Secretary: 0118 322 8145 (Office hours)
Haematology Ward: 0118 322 7470 (Out of hours)

4. Service Level/Third Party Agreements and Accreditations

Service Level/Third Party Agreements (SLA/TPA) are drawn up as part of written contract between the OxBMT/ACT Service and/or OUH, and the third-party provider. These are reviewed on a regular basis and revised as appropriate. The service also holds a number of accreditations and accreditations of services used are also listed.

The following table lists the Service Level/Third Party Agreements (SLA/TPA) and Accreditations applicable to the OxBMT/ACT Programme. The table indicates Licence/Certificate numbers where appropriate, date of issue and expiry, where the hard/electronic version is located and the clinical lead.

Table 1: Service Level/Third Party Agreements and Relevant Service Accreditations

SLA/TPA and Accreditations	Licence/Certificate Number	Date of issue	Date of expiry	Location	Lead/Organisation
Joint Accreditation Committee ISCT-EBMT (JACIE)	1055	04/11/2022	03/11/2026	JACIE reaccreditation 2021	Dr Andy Peniket (BMT)
Joint Accreditation Committee ISCT-EBMT (JACIE)	1057	09/03/2023	08/03/2027	SLA 2016	Dr Gurman Kaur SCI, NHSBT Rachel Pawson TAS, NHSBT
SLA: The Anthony Nolan Trust	N/A	21/05/2018	Renewed automatically annually	JACIE inspection 2020	Dr Andy Peniket
SLA: Stem Cells and Immunotherapy Services (SCI, NHSBT)		01/04/2022	31/03/2025	SLA	Dr Gurman Kaur
SLA: Therapeutic Apheresis Services (TAS, NHSBT)	N/A	01/04/2022	31/03/2025	SLA	Dr Rachel Pawson
SLA: Extracorporeal Photopheresis (NHSBT)	N/A	01/04/2022	31/03/2025	SLA	Dr Rachel Pawson

Department of Transplant Immunology & Immunogenetics, Churchill. CPA accreditation incorp ISO 15189	002	02/04/2020	01/04/2021	SLA	Dr Martin Barnardo
Department of Transplant Immunology & Immunogenetics, Churchill. EFI	03-GB-016.984	10/05/2023	10/05/2024	SLA	Dr Martin Barnardo
John Radcliffe Laboratory of Haematology, including Molecular diagnostics: UKAS accreditation	8464 - This accreditation covers the Haematology lab on all sites and includes molecular haematology and haemostasis	23/07/2020	30/06/2024	SLA	Andrew Platt
Churchill Hospital Blood count service/Blood Bank/Haemophilia Centre: UKAS Accreditation	8464 - This accreditation covers the Haematology lab on all sites, and includes molecular haematology and haemostasis	23/07/2020	30/06/2024	SLA	Andrew Platt
BHT Laboratory of Haematology follows quality management for UKAS accreditation	8464 - This accreditation covers the Haematology lab on all sites and includes molecular haematology and haemostasis	23/07/2020	30/06/2024	SLA	Andrew Platt
Royal Berkshire Trust	Currently RBT have a Service Specification with OUHT with a view	01/04/2021	31/03/2024	Service Specification	Andy Peniket and Asif Khan

	of RBT becoming a Level 3 Satellite unit of OUHFT					
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5. Definition of the Quality Management Plan

The quality management plan (QMP) supports the OxBMT/ACT programme and encompasses activity on the Churchill site and the unit at BHT and RBT. It also describes the interfaces with the NHSBT services.

The quality management plan ensures compliance with the related standards as described earlier and supports all processes related to the provision of care for sibling donors (allogeneic) or patients (autologous) undergoing PBSC harvest or lymphocyte collections, and for, patients receiving allogeneic or autologous BMT, or ACT therapies.

Quality management plan elements include:

- Donor selection, eligibility, management, and deviations
- Donor care
- Donor information
- Donor follow up
- Patient referral, selection, management
- Patient care
- Patient information
- Treatment delivery
- Patient monitoring
- Environment

Quality markers are based on a Clinical Governance framework and include:

- Risk management
- Compliance reporting
- Health and safety
- Training, education, and competence
- Morbidity and mortality review
- Clinical outcome audit
- Internal and external audit
- Quality monitoring and improvement
- Purchase of goods and services from other agencies
- Purchase and maintenance of equipment
- Document development and control
- Internal and external communication

These elements are described more fully in Section 8.

6. Service Aims

The aim of the OxBMT/ACT programme is to ensure the highest quality of care to donors and patients undergoing harvest and patients undergoing transplant procedures and advanced cellular therapies, and to seek to continually improve the level of service; this is focused on the following elements:

- Donors/patients are well informed about the harvest process, its risks and benefits and feel confident about their treatment, confidentiality and care.
- Patients are well informed about the transplant process, its risks and benefits and feel confident about their treatment, confidentiality and care.
- Patients are well informed about the ACT process, its risks and feel confident about their treatment, confidentiality and care.

- Policies, procedures, and guidelines are evidence based, regularly reviewed and audited for compliance.
- Outcome data are monitored regularly and are comparable with EBMT/BSBMT standards.
- Health and safety measures are enforced.
- Staffing levels are adequate to allow for the acuity of the patient group.
- Staff are sufficiently trained to carry out their work competently and undergo continuous professional development.
- Excellent communication and working relationships with the NHSBT, TAS and SCI and other third-party organisations.
- Environmental standards are maintained.
- Standards are monitored to ensure continual service evaluation and improvement using a robust clinical governance framework, including such elements as:
 - Clinical audit, internal and external
 - Monitoring of adverse events
 - Monitoring of donor and patient satisfaction through surveys and review of complaints and commendations
 - Risk assessment and management
 - Mutual participation between OxBMT/ACT and NHSBT services at the individual clinical governance meetings.

7. Roles and Responsibilities

The OxBMT/ACT programme is administered by the OxBMT and ACT teams and quality manager, within the Department of Clinical Haematology with links to the Department of Haematology at BHT and RBT. Organisational and relationship charts for all departments can be found in Appendices 4 and 5. The management structure defines the lines of responsibility for all members of staff and ensures that staff are provided with the resources and skills to carry out their defined roles and responsibilities as expressed in their job descriptions and person specifications.

Person specifications for all roles are held within individual job description or medical job plan. Service specific specifications are outlined in policy B.9.2. The specific responsibilities of the OxBMT/ACT and NHSBT teams are outline below:

OxBMT/ACT

Programme Director (PD) – responsible for the overall management of the OxBMT/ACT programme. This responsibility is delegated by the Director of Clinical Haematology or Clinical Director for Cancer and Haematology. The Programme Director is responsible for the implementation and maintenance of the quality management programme, ensuring good governance and liaison with third party providers. The PD holds an honorary contract with BHT and RBT.

Lead BMT Clinician -will lead the BMT service and deputise for the Oxford PD to carry out the above responsibilities within OUH.

Lead ACT Clinician - will lead the ACT service and deputise for the Oxford PD to carry out the above responsibilities within OUH.

BHT Lead Transplant Clinician – will deputise for the Programme Director to carry out the above responsibilities within BHT.

RBT Lead Transplant Clinician – will deputise for the Programme Director to carry out the above responsibilities within RBT.

Consultant Haematologists – are responsible for the medical management of individual patients and/or donors, ensuring that they receive appropriate treatment and monitoring in line with agreed protocols. They are responsible for the supervision of junior and middle grade medical staff.

BMT/ACT Fellow – Help to manage the day-to-day service requirements necessary for the flow of patients through the OxBMT/IEC programme. They also have an active role and specialist training in patients receiving BMT, DL and ACT therapies.

Commented [DR(O1)]: Added as we don't currently have BMT fellow but we will have ACT fellow

Ward Managers – are responsible for the operational management of the clinical areas, and the supervision of nursing staff and Health Care Assistants.

Advance Nurse Practitioners and Specialist Nurse Practitioners (ANP/SNP/) – are responsible for scheduling of the BMT/ACT programme, co-ordinating the pre-transplant work up, harvest, admission and follow-up care of BMT/ACT recipients in collaboration with a consultant. They provide support and information to potential and selected related donors, undergoing screening, work up and harvest, and patients undergoing harvest, BMT and ACT therapy. They act as a resource to the nursing team, other members of the multidisciplinary team and provide a link with referring hospitals and Anthony Nolan

Pharmacist – a specialist pharmacist serves each department and is responsible for the checking of all prescriptions, the education and support of the clinical team and the development and review of drug protocols in collaboration with the programme director. The Chief Pharmacist has overall oversight and responsibility for ensuring that all governance and regulatory aspects for the procurement, handling and administration of the ACT AT(I)MP are compliant with the relevant regulations, medicines policy and manufacturer recommended specifications and all staff involved in the processes have received the appropriate training required. A clinical Pharmacist has responsibility for completing the verification and approval of the ACT AT(I)MP product order, for receiving the ACT AT(I)MP product in the clinical area and dispensing for administration.

Dietician - All stem cell transplant and ACT patients are reviewed by a Dietitian during their admission. Nutritional assessment by the Dietitian provides advice on food safety, maintaining/improving nutritional status during admission (including symptom control and use of nutritional supplements) and identifies individuals who require nasogastric feeding or parenteral nutrition. High risk patients will also be reviewed by a Dietitian after their transplant/IEC therapy.

Quality Manager - responsible for the managing governance of the service, control and development of documents, the logging, reporting and /or investigation of incidents, complaints, and commendations, ensuring corrective actions take place; maintenance of records of audits and meetings; development of policy and ensuring cross referencing with providers documents such as NHSBT; working with the Programme Director to facilitate the QMP. The QM attends both the Clinical Haematology Clinical Governance meetings and the NHSBT Clinical Governance meetings ensuring a cross flow of information on governance, morbidity, and mortality issues. The QM coordinates regional autograft Quality meetings. The QM acts as liaison with license and accreditation organisations.

RBH/BHT Quality Administrator and Specialist Nurses - supports the quality aspect of the units by assisting with local document review and development, preparing for local inspections, liaising with

the quality manager regarding documents for the quality meeting including reviewed documents, incidents, and deviations.

Data Manager - ensures accurate completion of the required data submissions to EBMT/BSBMTCT, NHSBT, donor registries, and NHS commissioners. Liaises with BHT/RBT to ensure data is collated and recorded.

Data Manager (BHT) - ensures accurate completion of the required data submission to EBMT/BSBMTCT, NHSBT, submits data to Oxford for collation on OxBMT/ACT database.

Data Manager (RBT) - ensures accurate completion of the required data submission to EBMT/BSBMTCT, NHSBT, submits data to Oxford for collation on OxBMT/ACT database.

BMT MDT Coordinator (OUH) - supports MDT meetings by ensuring new referrals are captured and presented and ensures that documentation is filed in a logical, user-friendly system for future reference.

Information Manager (OUH) - undertakes application designs, to continue to build database scope and capacity; maintains the NSSG Haematology Website.

NHSBT Therapeutic Apheresis Service (TAS)

Programme Director/Medical Director - responsible for the overall management of the specialist therapeutic services, including collection service as detailed in the Oxford NHSBT Site Master Files and Quality Management Plans TAS and SCI.

Independent Related Donor Assessor – a Haematologist, who is responsible for the independent assessment, review, evaluation and consent, for related donors, for the OxBMT Service.

NHSBT Stem Cell and Immunotherapy Service (SCI)

Medical Lead - responsible for all medical aspects of the processing procedures; inter-department inter-hospital and ATMP facilities liaison regarding clinical activities and decisions

Laboratory Director - responsible for the provision of the laboratory service to hospitals, ensuring the laboratory maintains its standards and adheres to the guidelines prescribed in the appropriate accreditations.

8. Quality Improvement

The goal of continual improvement in the OxBMT/ACT service is achieved using the following strategies:

- Quality Audit – all elements of the peripheral blood stem cell collection facility and BMT and ACT processes are audited at least every 2 years –as per JACIE requirements. Audit is undertaken to review new practice/procedures or guidelines, in response to clinical issues/incidents and to ensure compliance with the Trust Mandatory audit programme. (Document B.1.8)
- Clinical Audit - a database of all transplants, ACT treatments and stem cell and lymphocyte collection procedures is maintained, and this provides annual and longitudinal outcome data that are reviewed at the BMT/ACT QM and MOG meetings. Other clinical audits are carried out intermittently.
- Outcome Data - data is submitted on a regular basis to EBMT with the corresponding annual reports from the BSBMT data base. NHSBT SCI PBSC/BM engraftment issues are

discussed monthly at the BMT/ACTQM. NHS England Specialist commissioning data dashboard, outcome data is submitted annually. Engraftment data is also reviewed annually at the Stem Cell Steering Group with NHSBT Services.

- Morbidity and Mortality (M&M) review - service data are collated using the M&M screening tool and are reviewed, on a monthly basis at the MOG meeting. Formal reviews are allocated as per OUH Trust policy. All BMT/ACT deaths in the Thames Valley are reviewed. These are logged by the QM, and quarterly data is fed back to the Trust.
- Adverse Events – are reported appropriately using the OUH/BHT, RBT, EBMT and HTA reporting mechanisms. Adverse events relating to blood products are reported via blood bank to SHOT/SABRE. Incidents are reviewed at the BMT/ACTQM and/or Clinical Governance meetings and will be referred to NHSBT as appropriate as described in policy H.2.32.
- Risk Management and Assessment – processes new to the department and those undertaken infrequently are risk assessed using the OUH processes. OxBMT/ACT review these at the BMT/ACTQM. Standard protocols are used at BHT/RBT. Wider issues pertaining to the department are addressed at the local MOG and Haematology/Oncology Directorate meetings.
- Protocol deviations: All protocol deviations are forwarded to the BMT quality manager and are discussed at BMTQM, planned deviations require prior authorisation using the ‘Planned deviation’ form by PD. Unplanned deviations are notified using the ‘Unplanned deviation’ form to PD and QM. Deviations are logged on a local spreadsheet to support deviation review and protocol refinement (Document B.1.2)
- Patient satisfaction – this is assessed in a variety of ways:
- Complaints - processed through the Trust Comments and Complaints Department, a summary of complaints is fed back at Clinical Governance to identify any necessary corrective actions.
- Commendations – thank you letters from patients are logged and a summary fed back to Ward and Clinical Governance meetings, these allow the team to gauge the elements of care that are important to patients and to provide staff with positive feedback.
- Patient Survey – all inpatients are invited to complete an OUH ‘Friends and Family’ form. Patients are invited to participate in the use of the Patient Experience Tracker (PET) at BHT. Feedback from these is addressed by the ward managers and reported back at Ward and Clinical Governance meetings.
- Incident review – As per policy H.2.32, Clinical Haematology, including OxBMT/ACT, incidents are reported via the electronic Ulysses system and managed in general by the ward manager and corrective actions are documented within the electronic system. BHT/RBT incidents are logged on a similar computerised reporting system. Reports are automatically forwarded to senior management and the clinical risk team. Through Ulysses ward managers collate incident information, analyse trends, and undertake corrective actions. Incidents pertaining to BMT/ACT (OUH/BHT/RBT) are reviewed, at the BMT/ACTQM. OxBMT/ACT SIRI are reported directly to the Programme Director and the relevant Clinical Director (OUH/BHT/RBT). Wider collation is reviewed and discussed at MOG meetings to ensure service learning.
- Training, Education and Competence – Ward Managers are responsible for the maintenance of nurse training, appraisal, and competency records. Nurses are required by the NMC to maintain their own CPD profile and revalidate every three years. All Medical staff are members of the College CPD schemes and are individually responsible for maintaining their own personal CPD portfolio which is reviewed at annual appraisal. Copies of junior medical staff competency are retained by the Clinical Haematology training lead. Management of these processes is outlined in policies B.9.1 and N.74.

- Research – The department undertakes both laboratory and clinical outcome research. Papers are submitted for publication. Current outcome research involves national and international studies.

9. Review of the Quality Management Programme

An annual Quality Management report (B.1.3) is produced by the quality manager reflecting the elements contained in the quality manual. It outlines changes, developments, and progress of the quality management plan. It provides an overview of audit, complaints, incident, SIRI, and compliments including annual transplant numbers and survival data. It is produced in March of each year. A copy of the report is submitted to the following meetings and personnel: BMT/ACTQM, NHSBT TAS/SCI services, MOG meeting, Oncology/Haematology Directorate meeting, OxBMT/ACT Programme Director, OxBMT Clinical Lead, ACT Clinical Lead, Clinical Haematology Clinical Director, BHT Lead Transplant Clinician, BHT Associate Director of Healthcare Governance, Cancer Services Clinical Director, Operational Manager (OUH & BHT/RBT), Lead Cancer Nurse (OUH & BHT/RBT)

The format is under continual revision due to on-going developments in the services requirements.

10. Documentation

The quality system is composed of a number of documents and these include:

- The Quality Manual (this document)
- Clinical policies, protocols, and guidelines
- BMT conditioning protocols
- ACT policies, protocols and guidelines
- TVSCN NSSG chemotherapy protocols
- Nursing policies, protocols, and guidelines
- Management policies and protocols
- Trust policies and procedures
- Standard forms
- Patient information leaflets

Documents are divided into 3 levels:

1. The Quality Manual
2. Policies and protocols
3. Standard forms

A complete list of documents can be found in Appendices 6 and 7.

11. Document Control

The process of OxBMT/ACT document development and control is defined in the Document Management Policy (H.25). In summary:

- A defined process is identified for the development and review of documents.
- Documents have a unique identifier, prefix letters denote the scope of the document, and the final number is the document number. The unique identifier, version, date of issue, document title and authoriser are recorded in the footer of all documents.
- Protocols, policies, and guidelines contain a review box, recording the type of review undertaken, version number, and date of next review, name, and designation of reviewer.
- Documents are officially validated at departmental meetings, protocol review days, BMT/ACTQM and depending on the focus, authorised by the relevant Clinical Director, BMT Clinical Lead or ACT Clinical Lead

- Documents are formatted by the quality manager with electronic versions available on the NSSG Haematology Website. They are logged and managed electronically within the Quality JACIE folder on the Oxford Oncology & Haematology Directorates secure drive by the quality manager (M drive)
- Previous versions are archived electronically for 10 years, by the quality manager.
- The quality manager maintains a log of all controlled documents, indicating current version numbers and review dates.

Access for documents and protocols is electronic on the NSSG Haematology Website. Protocols related to BMT are common between BHTRBT and the Oxford service. BHT/RBT documents are reviewed and conform to the local document control policy,

12. Patient Data and Confidentiality

Every patient has his or her own file identified with a unique hospital reference and NHS number. Patients are also logged onto the Trust's EPR or similar computer system. All documents relating to the patient are identified with the hospital reference number. Patient medical records are maintained according to the policy of the relevant Trust and retained in accordance with the relevant Trust retention policy Medical Records Department Policy. Electronic patient data is recorded, verified and maintained by the OxBMT/ACT programme and submitted to registries/EBMT/BSBMTCT/NHSBT only if written consent is obtained. All data are collected and stored in compliance with GDPR and Trust policy.

13. Related Donor Data and Confidentiality

Every related donor has his or her own file identified with a unique hospital reference and NHS number. Donors are logged onto the Trust's EPR computer system. All documents relating to the donor are identified with the hospital reference number. Donor medical records are maintained according to Trust policy and retained indefinitely. Donor notes are stored separately from patient notes. Donor notes are reviewed by an individual ANP/SNP and the medical assessor, and neither of these are directly involved with the recipient's care. Consent is sought from the related donor before health information can be shared with the treating consultant.

14. Accommodation

Cancer and Haematology Centre, Churchill Hospital, Oxford
A purpose-built facility opened in 2009.

Haematology Ward

25 beds: 10 single rooms with ensuite facilities, designated for allogeneic BMT recipients with switchable positive pressure and HEPA filtration, 5 standard single rooms, with ensuite facilities for general haematology patients and those undergoing high dose therapy and autologous stem cell rescue or ACT and 5 two bedded rooms, with shared ensuite facilities

Day Treatment Unit

This unit is for general haematology, selective BMT and ACT day case treatments and supportive care, some day case procedures i.e. central line insertion/removal. There is a designated area for BMT/ACT patients and a side room if isolation is required.

Triage Assessment Unit

A 4 bedded unit with an additional side room, to triage oncology and haematology patients 7 days per week (0800-2000).

Ambulatory Care Unit

A 4 bedded unit, providing ambulatory care for carefully selected oncology/haematology patients including peri and post-transplant allogeneic and autologous transplant recipients and ACT patients

Outpatient Department

An integral part of the Cancer and Haematology Centre comprising of 21 consultation rooms, 2 family sitting/counselling rooms and a large waiting room with a designated area for BMT/ACT patients.

Churchill Intensive Care Unit

Managed and run by the OUH Intensive Care service, this 8-bed unit: comprising 2 positive pressure isolation rooms and a 6-bed open unit.

Churchill Operating Theatres

The department has 8 theatres which are managed and run by the OUH Theatre Service.

Radiotherapy Department

Provides a comprehensive service for all tumour sites and Total Body Irradiation as part of conditioning treatment for allogeneic transplantation

Buckinghamshire Healthcare NHS Trust

Stoke Mandeville Hospital

Ward 5.

New purpose-built facility, designated for haematology

18 beds Haematology/medical ward:

4 ensuite single rooms with air filtration (designated for autologous transplant patients) with positive pressure and HEPA filtration

6 ensuite single rooms (general haematology/medical patients)

2 four bedded bays (one male, one female) for general haematology/medical patients

Cancer Care and Haematology Unit (CCHU)

This is a day unit with a designated area for follow-up and treatment of post transplant patients.

The haematology outpatient department is also based within this unit.

Wycombe Hospital

Sunrise Day Unit

This is a day unit with a designated area for follow-up and treatment of post transplant patients.

The haematology outpatient department is also based within this unit.

Royal Berkshire Foundation Trust

Adelaide Ward

This is a new purpose – build facility, designated for haematology and oncology with 22 beds available:

6 ensuite single rooms with air filtration with positive pressure and HEPA filtration

2 four bedded and 2 two bedded bays and 4 single rooms for general haematology/medical patients

All the single rooms have ensuite bathrooms

15. Internal Communication

There are a variety of structures and meetings in place for the management of the wider Cancer and Haematology services within the two NHS Trusts. OxBMT/ACT is represented at all levels, either by the Clinical Director, Programme Director or the Quality Manager. The meeting interface between BHT, NHSBT and OxBMT/ACT is displayed in the meetings organigramme (B.1.7), Appendix 4.

Oncology and Haematology Directorate Meeting (OUH)

Held monthly and chaired by the Oncology and Haematology Clinical Director, attendance includes, service clinical leads, operational manager, finance, lead cancer pharmacist. The main purposes of the meeting:

- Reviewing overall service provision
- Service operational management
- Performance management
- Policy decisions
- Complaints
- SIRI
- Governance issues
- Financial position and planning

Minutes are circulated via email to all attendees and Clinical Leads are responsible for cascading information to their services. Minutes are stored electronically by the directorate PA.

Clinical Haematology Operational and Governance Meeting (MOG)(OUH)

Operational:

Held monthly and chaired by the Haematology Clinical Lead, managed and minuted by a senior secretary. Attendance includes consultants and specialist trainees, ward manager, DTU manager, ACU manager, Triage Unit manager, ANP/SNP's, QMs, pharmacist, allied health professionals, information manager.

Main purposes of the meeting:

- Feedback from teams within the department
- Feedback from other meetings/forums
- Validation of new documents
- Budgetary review
- Policy decisions
- Operational management
- Service planning and review
- Management of national guidance

Governance:

Held monthly, directly after the operational meeting. Chaired by the Clinical Governance Lead, managed and minuted by a senior secretary. Attendance includes consultants, ward manager, DTU manager, ACU manager, Triage Unit manager, ANP/SNP's, QMs, registrars, pharmacist, allied health professionals, information manager and senior secretary.

Invited attendees include: ICU consultants, registrars, NHSBT QM and Senior Nurse and Microbiology consultant, registrars

Main purposes of the meeting:

- Monitoring and reporting incidents (Ulysses) and compliance with local and national safety targets (e.g. VTE, result endorsement)
- Review of all incidents graded orange and above
- Review of any serious adverse events, clinical incidents or complaints/compliments
- Formal review of all deaths (level 1) under the care of the Haematology department,
- Formal review (Level 2 or Structured Mortality Review) and reporting to Haematology department and Trust of any deaths raising concerns or learning opportunities,
- Feedback and learning from other clinical areas, teams and meetings
- Reporting and communication local and national alerts
- Audits and developments

Minutes are circulated via email to all attendees and managers are responsible for cascading information to their teams. Minutes are stored electronically.

Clinical Support Services Division Board Meeting (BHT)

Held monthly, attendance includes consultants, service managers, associate director of operations, associate director of nursing, lead cancer nurse, finance manager, HR, property services

Main purpose of the meeting:

- Budgetary review
- Performance management
- Operational management
- Service planning and review
- Validation of new documents
- Policy decisions
- Review of all incidents
- Review of any serious adverse events, specific incidents and complaints

Minutes are circulated via email to all attendees and managers are responsible for cascading information to their teams. Minutes are stored electronically.

Clinical Haematology Service Delivery Unit (SDU) Meeting (BHT)

Held monthly and chaired by the lead clinician, attendance includes consultants, ward manager, day treatment unit manager, clinical nurse specialists, cancer operational manager, and assistant director of operations, pharmacy manager, lead cancer nurse and senior secretary.

Minutes are circulated via email to all attendees and managers are responsible for cascading information to their teams. Minutes are stored electronically by the Clinical Haematology quality manager.

Clinical Haematology Clinical Governance Meetings (BHT)

Quarterly meetings chaired by the Clinical Governance Lead in conjunction with the Lead Cancer Nurse, Lead Cancer Manager and Senior Nurse for Cancer and Haematology. Results are reported back to the monthly SDU meeting.

The main purpose of the meeting is to:

- review of any critical incidents
- examine mortality and morbidity data
- review of adverse events

- review complaints and commendations
- consult and validate new policies or procedures
- audit results and development
- Intensive care admissions are reviewed on a 6-monthly basis.

Business and Clinical Governance Meeting (RBT)

Alternate meetings chaired by the Clinical Governance Lead in conjunction with the Lead Cancer Manager for Cancer and Haematology. The attendance includes consultants, service managers, administration staff, ward specialist nurse, other specialist nurses and the matron for the care group. The main purpose of the meeting is to:

- Do a budgetary review
- Review the performance management
- Discuss operational management
- Discuss service planning and review
- Discuss validation of new documents
- Review policy decisions
- Review of all incidents
- Review of any serious adverse events, specific incidents and complaints

Minutes are circulated via email to all attendees and managers are responsible for cascading information to their teams. Minutes are stored electronically.

Ward, Day Treatment Unit, Ambulatory Care Unit and Triage Unit Meetings

Occur regularly, chaired by the relevant ward/unit manager; incidents are reviewed as are complaints, service developments, policy development and change, and departmental operational issues. They also facilitate the free flow of information between the clinical areas and the MOG meeting. Minutes are circulated to the Matron, ward and unit teams. Minutes are stored electronically and in paper form by the ward/unit managers. At BHT these issues are dealt with at the SDU meetings.

OxBMT/ACT Quality Meetings

Allogeneic OUH operational

Monthly meetings are held, chaired by the Programme Director, agenda include:

- service development
- review of audits, engraftment, and outcome data
- protocol review and development
- incident and adverse event review
- ICU admissions, morbidity and mortality
- planned and unplanned deviations
- capacity and service development
- preparation for inspections.

Attendees include: programme director, ANP/SNP's, consultants, pharmacist, ward managers, QM, and NHSBT representative. Minutes are circulated by email. Minutes are stored electronically and in paper form by the QM.

Monthly regional autograft quality meeting

Attendees include: programme director, BHT lead transplant clinician, RBH lead transplant clinician, ANP/SNPs from all centres, consultants, ward managers, quality manager, NHSBT representative. Meeting objectives may include:

- service developments
- quality development
- quality support
- autograft programme development
- autograft audit
- review of local deviations and incidents
- review of related quality processes
- preparation for inspections

ACT Quality Meeting

Monthly meetings are held, chaired by the ACT Clinical Lead, agenda include:

- service development
- review of audits, outcome data
- protocol review and development
- incident and adverse event review
- ICU admissions, morbidity and mortality
- planned and unplanned deviations
- capacity and service development
- preparation for inspections.

Attendees include: ACT Clinical Lead, ACT Implementation lead nurse, consultants, ANP/SNP's, pharmacist, QM, and NHSBT representative. Minutes are circulated by email. Minutes are stored electronically and in paper form by the QM.

Site-Specific Multi-disciplinary Team (MDT) TVCN Meetings

These meetings are Thames Valley wide meetings involving those from the district hospitals

Lymphoma – A weekly meeting to discuss newly diagnosed, relapsed patients or those who require a change in treatment plan. Histopathology and radiology are reviewed

Myeloma – A fortnightly meeting to discuss newly diagnosed, relapsed patients and those who require a change in treatment plan. Histopathology and radiology are reviewed. Fortnightly local MDT

Myeloid – A fortnightly meeting, to discuss newly diagnosed, relapsed patients and those who require a change in treatment plan. Flow Cytometry, Cytogenetics and molecular diagnostics are reviewed. Fortnightly local MDT

A BMT consultant is present at each regional MDT and patients identified for Transplantation or ACT therapy are discussed, and appropriate referrals are made

Minutes and results are circulated via nhs.net by the MDT coordinators

BMT MDT (OUH)

Fortnightly meeting where new allogeneic BMT referrals are discussed, donor identification and suitability is reviewed, and scheduling agreed.

ACT MDT (OUH)

Weekly meeting where new ACT referrals are discussed, suitability is reviewed, and scheduling agreed.

BMT Weekly Outpatient Clinic Meeting (OUH)

A meeting following the weekly BMT clinic (Wednesday) to discuss all allogeneic BMT patients reviewed in the clinic on that day, discuss and agree treatment plans e.g. DLI and CD34+ top ups, and to update and educate all BMT team members. The programme director, consultants, registrars and NP's attend this meeting. Treatment plans are documented in each patient's electronic medical notes and proposed treatment type and date are listed on the DLI/CD34+Top Up Schedule, and issued weekly by the BMT Specialist Nurse.

Twice weekly ward MDT meeting (BHT)

At BHT all inpatients are reviewed at twice weekly meetings on a Monday and Thursday. Attendees include consultants, ward nurses, clinical nurse specialists, registrars, junior medical staff and pharmacist.

Royal Berkshire Foundation Trust MDT meetings

RBT have a weekly local and Thames Valley lymphoma MDT on a Wednesday afternoon.

This is attended by the consultants, ward clinical nurse specialist, the lymphoma specialist nurse, registrars & radiologist.

RBT have a have a local weekly 'morphology' MDT where we review blood films & bone marrows. This is attended by the consultants, ward clinical nurse specialist & registrars.

At RBT they have an alternate week Thames Valley myeloma MDT on a Thursday afternoon, and this is attended by the consultants, clinical nurse specialist & registrars and there is a Radiologist from OUH who dials in.

RBT have an alternate week Thames Valley myeloid MDT on a Thursday afternoon, and this is attended by the consultants, clinical nurse specialist & registrars.

Additionally, RBT also have a monthly BMT MDT with OUH on a Tuesday afternoon.

Joint NHSBT SCI/TAS and BMT Planning Meeting

This teleconferenced meeting is held weekly, Monday 12.00 – 12.30, to discuss all patients and donors on the peripheral blood stem cell harvest schedule, ACT patients scheduled for lymphocyte collection, and the BMT/ACT treatment schedule. Donor eligibility is assessed, and planned deviations recorded. This is attended by NHSBT processing staff, apheresis nurses, and BMT/ACT ANP/SNP's. OUH, BHT and RBT have separate dial in times.

BMTACT ward rounds

Oxford undertakes twice weekly consultant led and daily Specialist Registrar led ward rounds.

Consultants are available to review patients daily as required. BHT undertakes daily ward rounds.

16. External Communication

NHSBT TAS and SCI Clinical Governance Meeting

A monthly meeting to discuss the NHSBT clinical governance agenda. It provides a forum for raising and managing joint NHSBT/OxBMT/ACT governance issues. Attendees include TAS consultants, QM, lead nurse, clinic nurses and SCI staff, as well as the OxBMT/ACT QM. Minutes are circulated via email to the NHSBT team, attendees, the OxBMT/ACT PD and the HTA designated individual. The QM is responsible for feeding into the meeting and reporting back to BMT/ACTQM and storing electronic and paper copies.

Oxford Cellular Therapies Steering Group

An annual regional meeting attended by NHSBT consultants, quality managers, processing managers, apheresis staff, clinical nurse specialists, OUH, RBH and BHT Haematology consultants (Adult and Paediatric). Engraftment data and audits are reviewed.

Thames Valley Haematology NSSG Meetings

Held quarterly these meetings include an educational and business focus. Each educational meeting incorporates general teaching, disease/treatment specific audit, morbidity, and mortality data, and a BMT/ACT focus. The business meetings agree new haematology treatment options and protocols, as well as manage other NSSG business. Attendees include consultants, clinical nurse specialists and cancer managers from all Thames Valley hospitals. Minutes are circulated to the attendance list and are stored electronically by the NSSG.

JACIE Quality Managers Forum

Held quarterly around the UK, this meeting provides education, development, shared working and networking for quality managers working within BMT/ACT. This forum is attended at least annually by OxBMT/ACT QM. Minutes are circulated electronically.

17. Internal Audit

OxBMT/ACT carries out audits across all centres to assess implementation and effectiveness of the quality management system. Teams will ensure that timely corrective action is taken to address deficiencies, follow-up action taken and reported. The audits are also used to seek out potential opportunities for improvement. Ward based audits are undertaken to ensure compliance with the Care Quality Commission, Health service safety thermometer and OUH/BHT/RBT care standards. The audit process and resources are specified in procedure H.2.32.

18. External Audit

External audit and review are carried out via the JACIE and HTA mechanisms.

19. Equipment

Purchasing Equipment and Supplies

The departments at OUH, RBT and BHT control their purchasing processes to ensure that all purchased products and services that can affect the quality of service conform to specified requirements. Products and services are purchased from internal departments of each Trust or from external suppliers in accordance with the provisions and requirements of the Trusts' Standing Financial Instructions (SFIs).

Suppliers of products or services that can affect the quality of service are primarily evaluated by the Trusts, based on their ability to supply in accordance with specified requirements. Suppliers are dictated by the relevant Trust policy (e.g., other internal Departments of the Trust) and managed through Service Level Agreements (SLAs). Evaluation, periodic re-evaluation and selection processes are described in the Trusts' SFIs.

The Trusts' SFIs require that information clearly describing the product or service ordered is recorded on a written Requisition/Purchase Order and verified prior to release. Verification of purchased product or service is undertaken according to the Trusts' SFI's. Where medical equipment is involved, these are processed by the Clinical Engineering department.

Maintenance of medical equipment including patient monitoring and infusion devices

Equipment used within the BMT/ACT programme is suitable and safe for its intended purpose.

Ward managers' work with Clinical Engineering and the Trust to ensure equipment is appropriate, ensuring staff are competent in operating the equipment, have undertaken the local medical devices training, and that it is cleaned and stored appropriately. The Medical Equipment Engineering Department (MEED) at BHT and Clinical Engineering in Oxford and RBT are responsible for the regular inspection of the equipment and maintaining records. Equipment that is found to be faulty is removed from clinical use and reported to the appropriate department for inspection.

Equipment borrowed from the OUH Equipment library is also maintained to the Trust standards.

20. Human Resources

The Departments of Clinical Haematology identify its human resource requirements regularly and updates these requirements during the year in the event of any significant change. The process of recruitment, screening and validation is undertaken by the relevant Trust Human Resource departments.

Nursing staff

At OUH the Registered Nurse (RN) establishment is at a minimum 1 RN to 4 in patients with flexibility to accommodate a change in patient's clinical conditions. 13 staff have specialist qualifications. In BHT and RBT the registered nursing establishment should enable the ratio of registered nurses to patients to flex to accommodate a change in patient's clinical condition. This ensures that staffing levels take account of the acuity of the patient group.

At OUH all nursing staff undertake a 4-week orientation programme (refer to document H.26) followed by ongoing continuing professional development. This process is overseen by a designated mentor under the supervision of their team leader and the ward manager. Job descriptions and person specification define the scope of specific posts and the skills required. All staff is appraised annually using the values framework and produce a professional development plan.

Training requirements are achieved through supervised practice, competencies, informal teaching, formal teaching and academic training in chemotherapy, oncology, haematology, bone marrow transplantation and ACT therapies. Higher education is undertaken upon negotiation with the ward manager, this may include specialist cancer (BMT) degrees or modules.

Nurses (OUH, RBT and BHT) involved in the administration of cytotoxic drugs will have passed the module Care of the Patient receiving Cytotoxic Chemotherapy or will have completed APEL for their previous experience. The ward manager will determine with each individual through appraisal when nurses are ready to undertake this further training.

Nurses on the Haematology ward, responsible for the care of acutely unwell patients as well as patients undergoing allogeneic BMT/ACT therapy, attend an ALERT course, (or ILS for RBT/BHT) which teaches recognition and management of acutely ill patients. They also undertake specific transplant/ACT (ACT is at OUH only) based competencies (H.29a-f). Ward managers maintain records of staff training.

Specialist nurses and nurse practitioners are managed by the Deputy Matron for Haematology, they undertake specific training as laid down in the Cancer Service standards, are appraised annually, produce a professional development programme and an annual report which is tabled at the Department Management Meeting.

The person specifications for all posts form part of their job description. The person specification is written by the Matron and Ward Manager or Lead Cancer Nurse in line with Trust guidance.

Medical Staff

OUH: patients are cared for by a ward F2/CMT junior doctors, a specialist haematology registrar (SpR) and a consultant haematologist trained in transplantation/ACT therapy. Out of normal working hours medical cover is provided by a resident F2/CMT, supported by the non-resident 'on-call' specialist registrar and consultant haematologist. Daily ward rounds including weekends are performed by either the consultant or SpR. Consultants undertaking on-call for BMT/ACT patients have established competence in this procedure.

BHT: patients are cared for by a ward F1 junior doctor, supervised by either a haematology SpR or a general medicine ST2. These are in turn supervised by the ward consultant haematologist. Daily ward rounds including weekends are performed by either the consultant or SpR. Out of normal working hours medical cover is provided by a resident general medical F1 or ST1 supported by the non-resident 'on-call' haematology consultant.

RBT: patients are cared for by a ward F2 junior doctor/IMT, specialist nurse and haematology SpR. They are supervised by the ward consultant haematologist. The Consultant Haematologist conducts a ward round on a Monday, Tuesday & Thursday currently. New admissions/unwell patients are reviewed by the Consultant daily during weekdays and weekends as clinically appropriate.

Daily ward rounds including weekends are performed by either the consultant or SpR.

Out of normal working hours medical cover is provided by a resident general medical team supported by the non-resident 'on-call' haematology consultant and SpR.

RBH:

The Oxford department is a validated centre for training specialist Registrars, the Clinical Training Programme Director (Dr Murali Kesavan) is responsible for supervising training. Registrars maintain their training records and are appraised annually. The SpRs in RBT and BHT are on the Oxford registrar rotation.

Person specifications for all medical posts form part of their job plan but are also referred to in policy B.9.2.

21. General patient care

The provision of patient care is the responsibility of all personnel working within the BMT/ACT programme. The quality system defines and monitors the following aspect of patient care:

Patient registration and identification

Patients are registered onto the Trust EPR/PAS/CRS system and are assigned a unique patient registration number. All documents related to a patient will be identified with the patient's name and registration number. On admission to the ward, an electronic, bar coded wristband is placed on the patient.

Treatment protocols

All treatment protocols are subject to the document control system outlined in section 11. Patients are treated according to approved protocols.

Nursing care plans

Common nursing interventions are defined in core care plans, these documents are controlled according to the Document management policy (H.25) and they provide guidelines for the implementation of nursing care. Conditioning therapy care plans are an integrated part of the clinical protocol and kept in the patient's medical record for reference. Aspects of care not covered by core care plans are outlined in an individual care plan.

Documentation

In both Trusts the patient's medical records are used by all disciplines of staff to document clinical care and treatment. Entries are signed, dated, and timed with the discipline of the staff member defined. OUH has moved to electronic prescribing, observation recording and fluid balance for inpatient care. Electronic requesting of tests takes place in the inpatient and outpatient environment.

Written patient information

Disease specific information is given to patients using those resources produced by Macmillan Cancer Support, the Lymphoma Association or Leukaemia Research. In Oxford, treatment specific information is produced in-house and is subject to the department's document control policy and the Trust patient information guidelines. In RBT and BHT the treatment specific information used is Macmillan Cancer Support, the Lymphoma Association and Leukaemia Research.

Allogeneic BMT recipients receive: Blood Stem Cell and Bone Marrow Transplants: The Seven Steps booklet produced by Blood Cancer and additional in-house information

Autologous BMT patients receive: Understanding Stem Cell Transplants Using Your Own Cells (Autologous) booklet produced by Macmillan Cancer Support

ACT patients receive OUH ACT/CAR T cell information leaflets regarding the pathway and therapies they will receive the treatment they receive:

PBSC donors are given in-house information, Anthony Nolan booklet: Donating to Your Relative, HTA information leaflet and leaflets produced by the NHSBT.

All patients receive written and verbal information at relevant points of their treatment pathway. Any information given is documented in the patient's medical records.

Follow-up

Donors and patients are discharged from hospital at the discretion of a consultant (at BHT) or a specialist registrar (OUH). They receive verbal and written information from the medical and nursing team, and this is documented in their medical notes) Patients, who have had autologous procedures in Oxford, will be transferred back to their referring hospital for follow-up.

Patients who have had allogeneic transplant therapy will be followed up in the BMT and the DTU (OUH) as their condition dictates. Patients who have had ACT will be followed by the OUH ACT team for at least 30 days. Beyond this, follow up will be jointly in ACT clinic and referring centre.

Patients who have had autologous transplants in BHT will be followed up in the Wycombe or Stoke Mandeville day case units as appropriate, and RBT patients will be followed up at Royal Berkshire Hospital on West Ward Follow-up investigations are defined in procedures On discharge from hospital the district general hospitals and GP's will receive a discharge summary. Donors are followed up by their GP, but with a telephone follow up from a BMT ANP.

Documents include: B.2.13, B.3.10e, B.15 (electronic), B.15a, B.15b, B.15c, B.15d, B.21, B.33a, B.37, B.53a, B.62, B.64, B.76, N.102, CAR 8.0

Late Effects follow-up

This is undertaken within the general BMT clinic (Wed) and in a specific late effects clinic (Mon). B.15a

Teenage and Young Adult (TYA) services.

Facilities and plans for these services are under review within BHT and RBT. Oxford has a TYA lead nurse, an MDT and specific TYA facilities.

Triage Service (Oxford)

The triage service operates seven days per week 0800-2000. The service is staffed by band 5 & 6 nurses and led by a band 7 Team Leader. It is based on an Oncology ward adjacent to the Haematology ward. These nurses have undertaken specific BMT/ACT training and competency. Currently, the unit manager has extensive, specialist Haematology/BMT experience.

Outside these hours, patients and donors telephone the ward for advice and are referred to the on-call SpR as appropriate.

Triage Service (BHT)

Patients are triaged on the Haematology ward 5 by the senior nurse on duty. This is always a band 5 or 6 nurse who has completed specialist haematology/chemotherapy training.

Triage Service (RBT)

Patients who require 'unplanned' medical input out of hours contact Adelaide ward or attend A&E. If they contact Adelaide ward they are provided with appropriate advice by the senior nurse. During 'normal' hours they will either contact a specialist nurse or our senior day unit nurse for advice.

22. Health and Safety

The OxBMT/ACT programme operates within the health and safety policies of the relevant hospital trusts. These policies relate to issues such as:

- Infection control
- Cytotoxic management
- Disposal of sharps
- Spillage and disposal of cytotoxic drugs
- Manual handling
- Emergency disaster plan
- Intrathecal drug administration
- Fire
- Ward environment

All staff are screened for hepatitis B and vaccinated if appropriate; records are kept by the occupational health departments for each Trust. Staff history of Chicken Pox is documented by ward managers (Oxford). All staff are offered COVID vaccination and have access to regular lateral flow and PCR SARS-CoV2 testing.

Only staff that have undergone specialist training are authorised to administer cytotoxic drugs, administer stem cells and ACT therapy

The Clinical Haematology response in an Emergency is outlined by OUH documents and in document H.36 (OUH), the major incident plan (BHT 11) and the Incident Response Plan (RBT).

23. Key relationships

National Health Service Blood and Transplant (NHSBT) – John Radcliffe.

Details of this relationship are discussed in Section 3 and are specified in a service level agreement.

NHSBT – BHT

Details of this relationship are specified in the service level agreement.

NHSBT – RBT

Details of this relationship are specified in the service level agreement.

Blood transfusion laboratory – John Radcliffe Hospital, Stoke Mandeville and Wycombe Hospital.

The transfusion laboratories on all sites provide a 24hour service for the provision of all blood products, including irradiated and CMV negative units. The laboratories are CPA accredited.

Haematology and Biochemistry Laboratory – Churchill Hospital, John Radcliffe Hospital

The blood analysis laboratories on the John Radcliffe site provide a 24hour service. The Churchill site laboratory provides a 0800-1800 service.

BHT - Laboratories

The blood analysis and transfusion laboratories at BHT provide a 24hour service.

RBT - Laboratories

The blood analysis and transfusion laboratories at RBT provide a 24-hour service.

Pharmacy

OUH

There is provision for a 24 hour on-call pharmacy service. From 5.00pm until 11pm every day, the on-call pharmacist will be on site at the John Radcliffe hospital. From 11pm every day until 8am the following morning, the on-call pharmacist will be on call from home and can be contacted for urgent advice as needed.

There is a Haematology specialist lead pharmacist who supports the ward and DTU pharmacists and provides the service with document review support.

BHT

There is provision for a 24 hour on call pharmacy service. From 5pm to 9am every day the on-call pharmacist will be on call from home and can be contacted for urgent advice as needed.

RBT

There is provision for a 24 hour on call pharmacy service. From 5pm to 9am every day the on-call pharmacist will be on call from home and can be contacted for urgent advice as needed.

Cytotoxic drugs

OUH cytotoxic drugs and total parenteral nutrition are prepared and quality controlled by the Baxter Unit at the Oxford Science Park in Cowley. At BHT cytotoxic drugs are prepared by the Trust aseptic service unit. RBT drugs are prescribed by medical staff at registrar level or above using a computerised system. Prescriptions are screened and validated by a pharmacist before being sent to the relevant aseptic unit. Intravenous cytotoxic drugs are administered by nurses with specific training. IT chemotherapy is delivered according to the relevant Trust Intrathecal Policy.

The pharmacy department in OUH have mechanisms in place to ensure the correct handling and accountability for investigational drugs. The transplants in BHT and RBT do not involve investigational drugs.

The pharmacy department in OUH have pathways and mechanisms in place for the safe provision of ACT products.

Tissue typing laboratory

Tissue typing is carried out at the Transplant Immunology and Immunogenetics laboratory at the Churchill Hospital; this laboratory is accredited by Clinical Pathology Accreditation (UK) (CPA) and has European Federation for Immunogenetics (EFI) accreditation.

Specialist Consultants

At times the OxBMT/ACT programme will require the expertise of specialist consultants; a named representative is listed below although others will contribute as necessary. These personnel are employed by either the OUH, BHT or RBT Trust and are members of the appropriate specialist Royal College.

Speciality	Oxford University Hospitals	Buckinghamshire Healthcare NHS Trust
Surgery	Mr Bruce George	Mr Andrew McLaren
Pulmonary medicine	Dr John Park	Dr Anjani Prasad
Intensive care	Dr Elaine Armstrong	Dr Jarek Graniewski
Gastroenterology	Dr Phil Allen	Dr Ravi Sekhar
Nephrology	Dr Phil Mason	Dr David Mole
Infectious diseases	Dr Monique Andersson	Dr Chris Conlon
Cardiology	Dr Nik Sabharwal	Dr Piers Clifford
Pathology	Dr Daniel Royston	Dr Mavis Mayers
Psychiatry	Dr Lindsay Carpenter	Dr Karen Dauncey
Radiology	Dr Nia Taylor	Dr Carol Record
Radiotherapy	Dr David Cutter	Dr Nick Bates
Dermatology	Dr Rubeta Matin	Dr Ravi Ratnaval
Transfusion medicine	Dr Sue Pavord	Dr Liane Simons
Neurology	Dr Adam Handel	Dr Dennis Briley
Palliative and end of life care	Dr Matthew Carey	Dr Helen Pegrum
Gynaecology	Mr Simon Jackson	Dr Damian Eustace
Ophthalmology	Dr Martin Leyland	Mr Larry Benjamin

24. Development Plan Oxford

- Expand Ambulatory Services
- Expand Triage Services
- Expand accommodation for patient/donors

Author: Mandy Ellis, BMT Coordinator

Circulation

Oxford BMT Programme Quality Manual OUH, BHT and RBT
NSSG Haematology Website

Review

	Revision	Date	Version	Review Date
Mandy Ellis BMT Coordinator	Pre JACIE revision	May 2009	2.0	May 2010
Mandy Ellis BMT Coordinator	Post JACIE revision	Mar 2010	3.0	March 2011

Sandy Hayes Quality Manager	Formal incorporation of marrow collection facility	Jan 2011	4.0	Jan 2012
Dr Robin Aitchison	Formalisation of NHSBT services and relationships	June 2011	5.0	June 2012
Sandy Hayes Quality manager	Revision of appendices	July 2011	5.1	July 2012
Sandy Hayes Quality manager	Documentation of BHT arrangements	Apr 2012	5.2	July 2012
Sandy Hayes Quality manager	Assimilation of BHT and general up date	May 2012	5.3	May 2013
Sandy Hayes Quality manager	OxUH name change	Apr 2014	6.0	April 2016
Sandy Hayes, Quality manager	Post BHT JACIE inspection	June 2014	6.1	April 2016
Sandy Hayes, Quality manager	Update, commence inclusion of RBT	May 2015	7.0	May 2017
Joel Sedumedi Quality Manager	Update of SLA table post HTA	Dec 2017	8.0	Dec 2019
Robert Danby, BMT Consultant, Cristina Ovas, BMT Quality and Data Manager Denise Wareham, BMT Senior Specialist Nurse	Full review pre JACIE inspection	Mar 2021	9.0	Mar 2023
Robert Danby, BMT Consultant, Cristina Ovas, BMT Quality and Data Manager Denise Wareham, BMT Senior Specialist Nurse	Addition of RBT, satellite unit information Addition of ACT therapy General updates	June 2021	10.0	June 2023
Denise Wareham, BMT Senior Specialist Nurse	Removed document reference H.2.34 as this has now been archived and superseded by B.9.1 & N.74 Changed document no H.2.31 to B.1.8	Sept 21	10.1	Sept 2023