WESSEX BLOOD and MARROW TRANSPLANTATION UNIT

ANNUAL REPORT

2014
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INTRODUCTION

The Wessex Blood and Marrow Transplantation Unit (WBMTU) opened in December 2001 and the first patient received an allogeneic stem cell transplant in February 2002. At the end of 2014 1016 patients (1104 procedures) have received a transplant, 373 allogeneic (435 procedures), 148 sibling, 225 volunteer unrelated donor and 643 autologous (669 procedures). Activity for 2014; 144 total transplants, 60 allogeneic (20 sibling and 40 volunteer unrelated donor), 84 autologous.

The transplant unit has a total of 21 rooms, 12 with Hepa-filtered air, a small ante-room for hand washing and gowning and en-suite bathrooms. The transplant unit is integrated into the haematology ward (C6L) in Southampton General Hospital where patients receive intensive chemotherapy for leukaemia, myeloma and related disorders under the care of haematology and transplantation trained nursing staff. There are a further 9 neutral pressure single rooms on the ward. Patients undergoing allogeneic (donor) stem cell transplants are nursed in the Hepa-filtered rooms (high quality air with reduced bacterial and fungal spore contamination).

Out of core working hours transplant patients have emergency access to the MacMillan Acute Oncology Service, providing 24 hour, 7 day cover with 3 beds and 3 chairs available for use.

The first year of activity (2002) was a period of team building and planning with the preparation of protocols, standard operating procedures and development of treatment pathways. These continue to be reviewed and modified. An important early requirement was to develop efficient communication networks with the referring hospitals. Patients continue to be referred for transplant from consultant haematologists and oncologists in the following hospitals:

Portsmouth Hospitals Trust; St Mary’s Hospital, Isle of Wight; North Hants Hospital Basingstoke; Royal Hants County Hospital Winchester; Royal Bournemouth Hospital; St Richard’s Hospital Chichester; Poole Hospital; Salisbury District Hospital; Channel Islands; Dorchester.

In 2014 we started a new satellite service with Salisbury Hospital. Patients receive their stem cell collection and after care post autologous stem cell infusion in Salisbury. Staff are currently working towards meeting the recently published version 6 standards for JACIE accreditation and will be joining with us for our next inspection in 2017.

Representatives from each of the referring centres meet on a regular basis (the Wessex Blood and Marrow Transplantation Clinical Forum), which reports to the Central South Coast Cancer Network. The Clinical Forum is an important group of haematology specialists that co-ordinates the provision of the transplant service, allowing full involvement of experienced personnel in the region. The group meet once a year in the autumn for an Activities and Outcomes meeting where all SCT units in the region present.

Kim Orchard Transplant Director

Carol Hurlock BMT Quality Programme Manager
QUALITY MANAGEMENT PROGRAMME

The Quality Management Programme (QMP) was established in 2002. Meetings are held every 2 months and attended by representatives from all departments involved with the treatment and care of patients undergoing stem cell transplants. The meetings are the mechanism by which standards are set and maintained for the provision of care to patients throughout the transplant process and link into the Cancer Care Group and Divisional Governance meetings within the Trust. The agenda regularly includes Risk/Adverse Events, Data/Information, Specific areas of activity, Guidelines and Policies, Audit, Training and Development. In 2014 Salisbury Hospital joined the WBMT QMP as a Satellite centre to ensure consistent standards of treatment and practice.

Inspections
In 2014 the apheresis unit underwent its third HTA inspection and our licence was maintained. The inspectors report highlighted only one minor corrective and preventative action (CAPA); “The WBMTU cell collection facility (apheresis unit) will arrange to undertake an independent audit with another licensed facility”. This will be conducted as a reciprocal audit with the Piam Brown Ward, Southampton General Hospital cell collection facility. Our next JACIE full inspection will be in 2017 (re accredited April 2013) with an interim inspection of documentation due in 2015. Salisbury is currently aligning policies and procedures to ensure we meet the latest JACIE version 6 standards published in March 2015.

The quality management system Q-Pulse (Gael Quality Ltd.) is now integral to the functioning of the QMP for both document management and the reporting of risk/adverse events. Salisbury Hospital also has access to Q-Pulse for staff to read and acknowledge documents assigned according to their role within the transplant service.

Risk/Adverse Events
In conjunction with Trust requirements and Policy all BMT incident, near miss and planned deviations are raised and actions recorded in Q-Pulse. The BMT CNS has QMP clinical responsibility for the management of all BMT incident and near miss events and the Transplant Director provides final review and sign off. In 2014 a total of 29 transplant related incident and near miss events were reported with an overall total of 133 raised in Q-Pulse until the end of 2014. Planned deviations are also reported in Q-Pulse; 12 in 2014 with a total of 95 raised.

Below shows the number of incident/near miss events raised under each category:
Documents
There are 132 BMT controlled documents currently in use and these are reviewed every two years or before, as necessary. Staff groups are kept up to date on the system and assigned specific documents that they are required to read/acknowledge to support both treatment and education/competency requirements.

Audits
Each year there is a planned programme of audit undertaken and presented. In 2014 12 audits were completed. These are reported as per Policy to the Trust with recommendations and actions recorded.

2014 Audit Programme

<table>
<thead>
<tr>
<th>TITLE</th>
<th>ACTIONS</th>
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</thead>
<tbody>
<tr>
<td>Haematology donor, allogeneic and autologous transplant case note audit</td>
<td>Changes to improve filing and recording essential data to support meeting standards</td>
</tr>
<tr>
<td>Myeloma day case priming</td>
<td>No changes required</td>
</tr>
<tr>
<td>Cyclosporin re audit</td>
<td>Changes to medical staff documentation requirements. Education to medical &amp; nursing staff</td>
</tr>
<tr>
<td>Compliance of checking pregnancy in donors</td>
<td>Medical staff education reminder to record pregnancy assessment on the autologous donor assessment sheet.</td>
</tr>
<tr>
<td>Re audit compliance with G-CSF dosage as per policy on G-CSF administration</td>
<td>File a copy of the 2nd page of the prescription in the patient’s notes to ensure all required drugs have been issued/checked by the nurse.</td>
</tr>
<tr>
<td>Re audit Platelet monitoring in autologous and allogeneic stem cell donations</td>
<td>No changes required</td>
</tr>
<tr>
<td>Re audit Stem cell traceability from donation to re infusion</td>
<td>Education reminder to monitor and ensure the UPN is recorded on all harvesting procedure sheets</td>
</tr>
<tr>
<td>Re audit presence of medical order in the Cell Collection Facility</td>
<td>No changes required</td>
</tr>
<tr>
<td>Re audit of eDocs discharge summaries</td>
<td>New template created for junior doctors to include essential transplant in patient information in the discharge summary. Reminder to send to referring hospitals for follow up</td>
</tr>
<tr>
<td>Consent audit</td>
<td>Ensure harvest consent forms are countersigned by the medical practitioner</td>
</tr>
<tr>
<td>Anti –emetic audit for melphalan</td>
<td>No changes required</td>
</tr>
<tr>
<td>WBMT clinical coding procedures</td>
<td>Errors identified and amended monthly/as identified</td>
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Morbidity and Mortality
All transplant patient deaths are reviewed and regular M&M meetings are held to present, discuss and provide education/learning for those patients that have either died within 100 days of transplant, died of transplant related cause, post mortem performed or ITU admission. In 2014 ten allogeneic transplant patient deaths were reviewed at monthly M&M meetings held.

Education, Training and Competency
There is an active and progressive approach to education, training and competency in BMT within all health care professional groups ensuring high standards of quality and care for transplant patients.

Carol Hurlock, BMT Quality Programme Manager
STAFFING

Consultants & Associate specialist
Dr Kim Orchard (Transplant Program Director), Dr Deborah Richardson (Lead Consultant for donor issues and stem cell harvest), Dr Matthew Jenner (Haematology Consultant), Dr Andrew Davies (Medical Oncology Consultant), Dr Srin Narayanan (Haematology Consultant), Dr Andrew Duncombe (Haematology Consultant) and Professor Peter Johnson (Medical Oncology). Dr Kate Hill (Associate Specialist in BMT, lead for late effects and donors).

Junior medical staff
1 BMT Fellow, 1 Lymphoma Fellow (care for transplant and non transplant patients), 1 SpR (Haematology training rotation); 2 SHOs (medical rotation). All junior staff care for transplant and non-transplant patients.

On-call arrangements: Resident on-call SHO, non-resident SpR, consultant cover as required for JACIE accreditation on a 24 hour basis.

Nursing
The unit has a team of dedicated nursing staff experienced in the care of patients undergoing stem cell transplantation or receiving intensive chemotherapy for acute leukaemia. In 2014 Nurse Practitioners were introduced with 2 experienced haematology nurses appointed to support medical staff and nurses on the ward. These roles are currently in development as the staff undertake the training programme. The majority of ward staff are Band 5 or above, reflecting the specialist type of patient care required. The ward manager is an experienced Band 7 sister, Stephanie Churchill, supported by 4.3 ward lead sisters. The transplant programme is supported by five senior nurses with extensive allogeneic and autologous transplantation experience; the BMT Lead Nurse (Sister Nikki McKeag); the BMT Clinical Nurse Specialist (Sister Joan Newman), the allogeneic specialist nurse stem cell transplant co-ordinator (Sister Sara Main) and the autologous specialist nurse stem cell transplant co-ordinator (Sister Jane Lamb) and the Lead Apheresis Nurse/Haematology Day Unit Manager (David Hutchins).

Quality management
Mrs Carol Hurlock manages the quality management programme and provides line management to the Data Manager and Office Manager.

Data collection
Mrs Linda Jarvis manages the BMT data, primarily to ensure that the EBMT receive our transplantation data accurately and in a timely manner but her role also includes supporting and in putting data into the BMT hospital integrated clinical support system, identifying stems cells that no longer require storage (deceased patients or clinical decision) for the Stem Cell Laboratory to destroy, data collection for audit and research studies and providing data information as required, both internal and external requests.

Office management
Mrs Mary Joseph provides essential administrative support to the Quality Manager and the BMT clinical team to ensure the smooth running of the BMT Office.

BMT care co-ordination
Mrs Wendy Spencer provides administration support to the autologous and allogeneic transplant co-ordinators, booking appointment slots, sending letters, answering telephone queries, circulating transplant schedules etc.

Salisbury satellite centre
Dr Jonathan Cullis (Consultant), Dr Louise Fraser (Consultant), Dr Effie Grand (Consultant), Roy Dear (Clinical Nurse Specialist)
Wessex Blood and Marrow Transplantation Unit
Annual Report 2014

C6L WARD

Ward nursing staff –
Actual Workforce Budget figures for 2014

<table>
<thead>
<tr>
<th>Band</th>
<th>Figure</th>
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<tbody>
<tr>
<td>7</td>
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</tr>
<tr>
<td>6</td>
<td>4.3</td>
</tr>
<tr>
<td>5</td>
<td>30.82</td>
</tr>
<tr>
<td>2</td>
<td>1.0</td>
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For many years C6L had very little staff change/turnover but in 2014, 10 members of staff left the ward and 6 joined, including 2 new Band 6 nurses increasing this staffing level. By the end of the year the overall vacancy level was 6.23 with an additional 3.6 planned to leave early in 2015. Reasons for these staff leaving varied from a long standing Band 6 nurse moving abroad, career advancement/role change and the working pressures of caring for BMT patients.

Other staff –
In addition to the nursing staff the ward is supported by 2.0 WTE Band 1 Housekeeper posts with 1.8 in post and 1.0 WTE Ward Clerk, currently covered by 2 part time staff in post. There is also a Band 3 (0.67) Ward Secretary role that was vacant for approximately 2 years and appointed in 2014 but unfortunately became vacant again after 3 months, due to personal unforeseen circumstances. This role also supports the TYA Unit and C7 (Haematology Day Unit).

Training and Development
Attendance on study days has proved challenging due to reduced staff numbers but specific courses attended include; Chemotherapy course, caring for high dependency patients, TYA course, mentorship, care of the patient with cancer, as well as statutory and mandatory Trust training. Individual staff completed dissertations for degree qualifications and career development. Band 6 nurses have a quarterly development study day that includes all cancer care nurses at this level. Two of these study days are held with Band 7 nurses. The C6L Band 7 organises all Cancer Care Band 6 development study days. In addition, regular ward meetings are held to update staff on Ward, Care Group and Trust matters. In 2014 the Band 7 completed the Nurse Prescribing Course focusing on IV electrolytes. How this role supports the Unit is still under development with staff shortages and the Supervisory Ward Leader role not as yet funded/in place.

Ward –
From December 2013 to April 2014 several transplant rooms were severely affected by water ingress from building works being carried out above the Unit. Temporary accommodation was used for these patients on D level, resulting in the nursing team caring for patients on both C and D level until the problem was rectified and patients could be safely transferred back to the Ward. The Trust was kept fully aware of the ongoing issue, a full serious incident report was completed and the problem is now resolved.

TEENAGE AND YOUNG ADULT UNIT (TYA)
The Regional TYA unit was opened in September 2013 providing cancer treatment for teenagers and young adults aged 16 – 24 years. It also provides for this age group undergoing autologous and allogeneic transplantation requiring readmission for the management of complications. The unit was designed with input from previous TYA patients to ensure it met the specific user needs of this age group. It has six large inpatient en suite rooms and a day case area with four treatment spaces which caters for young patients receiving day case chemotherapy and supportive care. It also has a large social space vital for the needs of this patient group. Although the TYA unit is staffed separately to C6L the two areas work closely together to share knowledge and expertise.

Sister Stephanie Churchill, Senior Sister C6L & TYA
C7 APHERESIS UNIT

In September 2013 the new Haematology Day Unit opened serving all haematology patients requiring day case treatment including a 3 bedded apheresis bay, which performs stem cell harvesting for patients and donors, plasma exchanges, leukopheresis and ECP (the ECP service started 5 years ago). The day unit treats patients undergoing transplantation, delivering chemotherapy, donor lymphocyte infusions, blood product support, fluid and electrolyte infusions, procedures such as bone marrow biopsies and line removal. There are 2 side rooms alongside the 6 chair treatment space, ensuring that patients are protected from infection. The day unit also has a purpose built pentamidine nebulizer room, ensuring comfort and safety for the patients.

Staffing - The Lead Apheresis Nurse/Haematology Day Unit Manager is supported by 10 trained nursing staff, 2 health care assistants and 2 reception staff. 5 trained members of staff, besides the Lead Apheresis Nurse are also trained in all apheresis procedures.

Activity in 2014
- PBSC Collections
  In 2014, 105 patients had peripheral blood stem cells harvested
- DLI
  In 2014, 51 patients received 123 donor lymphocyte infusions with the main indication being pre-emptive treatment for post allograft patients.

Deborah Richardson, Cell Collection Facility Director

OUTPATIENTS

There are a number of outpatient clinics held each week; two transplant referral/planning consultant led clinics, Weekly nurse led clinics for recently discharged allograft patients, weekly allograft follow clinic and the late effects clinic. Donors are seen by the Associate Specialist in a specified donor clinic setting. In 2014 there were a total of 2,131 attendances; 111 were new patients and 2,020 follow up appointments.

  Late Effects Clinic - started in 2010 seeing patients discharged from the weekly allograft follow clinic that are off immunosuppression, have normal immune constitution and/or have completed DLI’s. In addition, paediatric transplant patients are discussed at a joint MDT meeting and then transferred in a twice yearly joint transition clinic held with a consultant Paediatrician. 8 to 10 young people are transferred each year and currently the Late Effects Clinic has a total of 208 transplant patients on the list.

SALISBURY HOSPITAL

In 2014 Salisbury joined the WBMT service as a new satellite unit for patients to undertake stem cell collection and after care post autologous stem cell infusion. There were 13 referrals for autologous transplant from Salisbury in 2014; with 6 patients under the new service arrangements returning to Salisbury 24 hours post stem infusion, if clinically appropriate and a bed available for transfer. We are currently working with clinical staff in Salisbury to meet the recently published version 6 standards for JACIE accreditation to enable them to join with us for the next WBMT inspection in 2017.
INFECTION CONTROL

Microbiology report, C6L
The WBMTP is supported by specialists within Microbiology and Virology with regular meetings (two per week) and direct communication for any urgent cases. An important factor in the care of patients receiving intensive chemotherapy for leukaemia and stem cell transplantation is the use of prophylactic antibiotics, particularly the quinolone antibiotics, for example ciprofloxacin. There has been concern in some units that the use of quinolones leads to an increase in antibiotic resistance and possibly an increased incidence of *C. difficile* infection. The data shown below in graph 1 indicate the crude number of Gram negative bacteraemia episodes within the C6 ward over the period 2009 – 2014. The commonest organisms causing gram negative bacteraemia over the 6 year period 2009 – 2014 were E. coli (33%) and Pseudomonas sp. (22.6%), followed by Klebsiella sp. (8.7%), Acinetobacter (7%) and Stenotrophomonas (6.1%). The data include all patients treated within the ward environment, patients receiving intensive chemotherapy for leukaemia and those undergoing autologous or allogeneic stem cell transplants.

Graph 1

The data indicate that there has been a relatively steady level of Gram negative bacteraemia incidence in patients treated on the ward with no indication of any underlying upward trend.

Incidence of quinolone resistant Gram negative bacteraemia.
The use of quinolone antibiotics for prophylaxis in neutropenic patients has been associated in some reports with an increase in the incidence of resistant Gram negative organisms. The data shown in graphs 2 and 3 summarise ciprofloxacin resistance in Gram negative bloodstream infections (anaerobes and Stenotrophomonas have been excluded).

Graph 2

Graph 3
The data indicate that there has been no significant change in the proportion of ciprofloxacin resistant Gram negative organisms isolated from patients in the period 2009 – 2014. As the overall activity on the unit has increased in this same period it is likely that the incidence of Gram negative infections and antibiotic resistant isolates is at least stable and may be falling.

Resistance to piperacillin-tazobactam and/or gentamicin in Gram negative bloodstream infection

Current trust policy for the antibiotic treatment of febrile neutropenia comprises a first line antibiotic regimen of piperacillin-tazobactam, with the addition of gentamicin if the patient has high-risk features (related to underlying disease, treatment regimen, or severity of sepsis).

The data shown in Graph 4 summarise resistance to piperacillin-tazobactam and gentamicin in Gram negative bloodstream infection isolates (anaerobes and stenotrophomonas excluded).

Graph 4

The numbers are small but there was an apparent increase in resistance (among aerobic gram negative isolates) to first line therapy in 2014. This was due to two bacteraemias with resistant *Klebsiella sp.* (one of which was an ESBL producer) and one resistant *E. coli* bacteraemia. This should be kept under review to ensure that this is not an emerging trend.
Bloodstream infection due to ESBL-producing enterobacteriaeae
Some Gram negative organisms produce Extended Spectrum Beta Lactamase (ESBL). These enzymes render the organism resistant to many beta-lactam antibiotics and these organisms may in addition display resistance to other classes of antibiotics. ESBL enzymes may be transmitted between organisms and may spread within units. Graph 5 shows that the incidence of bloodstream infection with ESBL-producing *E coli* appears to have reduced. There were only two bacteraemias with ESBL-producing Klebsiella species in 2014.

Graph 5

![Bloodstream infection with Gram negative organisms producing Extended Spectrum Beta Lactamase (ESBL)](image)

Vancomycin-Resistant Enterococcus (VRE)
The data in graph 6 show the number of bloodstream infections (6a) and number of patients colonised (6b) with vancomycin-resistant enterococcus (VRE).

Graph 6 a and b

![VRE bloodstream infection](image)

![VRE colonisation (all sample types)](image)

Isolates of vancomycin resistant enterococci (VRE) remain low but with a small increase in 2013 and 2014. It is not clear whether this is a sustained rise but closer controls of the use of vancomycin have been introduced. In these two periods there were patients with long admissions who were known to be carriers of VRE and who had recurrent VRE bacteraemia. Typing was performed on 4 VRE isolates in 2013 and 2 in 2014 and no evidence of cross infection was found.
MRSA

Graph 7

New Cases of MRSA Colonisation 2009-2014

Graph 7 shows the annual incidence of new cases of MRSA colonisation in patients on the unit. There appears to have been a fall in the incidence since 2010, possibly reflecting the use of topical decontamination procedures and pre-admission screening.

Clostridium difficile

Graph 8

The incidence of toxin positive *C. difficile* infection on the unit is shown in graph 8. The data include the incidence of infections acquired within UHS and in patients thought to have been already colonised before admission (defined as a *C. difficile* toxin positive sample within 72 hours of admission).

Bacteraemia with non-tuberculous mycobacteria (NTM)

Bacteraemia with NTM occurred in one patient per year from 2010-2013, and in two patients in 2014. The mycobacterial isolate from 2010 was not identified; all other isolates have been identified as *Mycobacterium chelonae*.

Summary:

Despite increasing numbers of patients receiving treatment within the C6L ward there has been no major increase in the incidence of multiply resistant organisms isolated and characterised by the department of microbiology. There were 3 episodes of bloodstream infection with gram negative organisms resistant to first line therapy in 2014, compared with one in the previous 3 year period. This will be kept under review. There has been a small rise in the number of cases of *C. difficile* infection, though overall numbers of cases are still very small (1 UHS-acquired case and 4 community-acquired cases).

Sarah Glover, Infection Control
DONORS
Donor Characteristics - 30 sibling donors were assessed in 2014 (2 for two procedures) for 28 recipients (2 recipients had 2 matched donors). The age range was 26-67; 14 male and 16 female and 23 England based; 7 overseas – Australia, Hong Kong, New York, Germany, Falkland Islands, Morocco (2)

Donor Abnormalities
- 1 female donor was iron deficient with a mild anaemia (3 young children)
- 1 donor had abnormal LFTs related to lifestyle factors
- 2 donors had asthma/COPD
- 3 donors had known pre-existing hypothyroidism
- 2 donors had LVH on ECG
- 1 donor had known hypertension – well controlled
- 2 donors had previous back issues – discectomy/sliped disc
- 1 donor had a previously elevated CA125 – negative investigations for malignancy
- 1 donor had a history of recurrent BCC – all excised
- 1 donor had previous renal carcinoma treated by nephrectomy alone 15 years previously.

We performed a risk assessment as regards using this donor and concluded that bone marrow harvesting would be safe for the donor and using a matched sibling would be safer for the recipient than a miss-matched unrelated donor. Recipient and donor were counselled about this issue prior to transplant.

Harvest Results
Of the 30 donors assessed in 2014:
- 20 donors had stem cells and/or donor lymphocytes harvested
- 3 have had stem cells harvested in 2015
- 3 have dates planned for harvest in 2015
- 2 donors another sibling was chosen
- 2 donors are not required to donate as the recipient has died

22 donors had stem cells and/or donor lymphocytes harvested and of these 3 had been assessed initially in 2013

Stem Cell Harvests 2014
20 donors harvested (14 peripheral access / 4 central access):
- 17 by GCSF/peripheral blood route
- 2 by bone marrow harvest
- 1 by GCSF/PB and BM harvest
  - 10 harvested in 1 collection with DLIs frozen at same time
  - 6 harvested sufficiently with 2 collections with DLI stored from 2nd day
  - 1 harvested in 2 collections but insufficient for DLI storage as CD34 dose less than target
  - 1 harvested poorly (1.38x10^6/kg on Day 1 so underwent BM harvest on Day 2.
  
Subsequently found that donor had primary CMV infection at time of harvest.

2 had a bone marrow harvest (donor with previous renal carcinoma and donor for second allograft)

DLI harvests 2014
5 stand alone DLI harvests –
- 2 receiving ongoing DLIs and original donations infused
- 2 as original harvest was PB/BM harvest with poor total stem cell doses so none stored at that time
- 1 harvested as part of the PROT4 trial (Prophylactic Transfer of CD4 Lymphocytes)

Complications
1 bone marrow harvest donor had significant post-operative haematomas which delayed discharge due to pain and reduced mobility. No delayed long term symptoms.

Kate Hill, Associate Specialist BMT
NHSBT TOOTING

Histocompatibility and Immunogenetics (H&I) Service
The H&I Department at NHS Blood and Transplant in Tooting provide support for haematopoietic stem cell and renal transplant programs for a number of transplant units in the South of England. In addition the laboratory provides immunogenetic services for a variety of diseases, investigations of transfusion related immunological reactions and provision of HLA and HPA compatible products when required.

The H&I laboratory is accredited by Clinical Pathology Accreditation (UK) Ltd (CPA) and European Federation for Immunogenetics (EFI) for the clinical services it provides. It is also MHRA licenced. There are 24 members of staff, the majority being clinical scientists, and the department is lead by a Consultant Clinical Scientist.

The Laboratory began H&I support for the HSCT program in Southampton in September 2010. This service now includes:

- HLA typing patients and family members
- Initiation and coordination of unrelated donor searches
- HLA antibody screening
- Advice regarding final donor selection
- Weekly attendance at the BMT planning meeting
- Post transplant cell lineage specific chimerism monitoring

There is close liaison between staff at the H&I department and the clinical team in Southampton. The service is lead by Shahram Hemmatpour, an experienced senior clinical scientist in H&I and is supported by a team of 6 clinical scientists in the laboratory. Attendance at the BMT planning meetings is by Shahram or Dr Deborah Sage (Consultant Clinical Scientist and Head of Department).

The Donor Search Process
Patients referred for an allogeneic haematopoietic stem cell transplant are HLA typed along with any potential related donors, generally siblings. In addition, and depending on clinical urgency, a search of the unrelated donor registries is undertaken. The search initially looks at donors within the UK and if necessary, worldwide. If there are no suitable HLA matched related donors, an unrelated donor option is explored and confirmatory typing samples are requested for, on average, 3 unrelated donors for each patient. HLA typing of the unrelated donor takes place to determine the HLA matching level. Ideally a 10/10 HLA match is found (i.e. matched for HLA-A, B, C, DRB1 and DQB1). In addition ABO compatibility and CMV matching is taken into account when searching for and identifying the final donor for transplant. On occasions, a fully matched 10/10 donor is not identified, and in these cases a 9/10 donor may be sought.

Laboratory developments
During 2014 the H&I laboratory underwent an extensive refurbishment program, allowing scope for future expansion and development of clinical services.
H&I Activity in 2014

Patient HLA typing referrals in 2014
In 2014, 105 patients were referred for HLA typing and of these 97 proceeded to an unrelated donor search. In total, 185 searches were initiated (97 UK, 62 International and 28 repeat searches). The outcome of the HLA typing referrals is summarised below:

- 105 patients HLA typed
  - 2 No donor found
  - 14 Searched but no VUDs requested
  - 8 HLA typed only – no further work

Unrelated donor CT sample requests in 2014
Confirmatory typing samples were requested from 475 unrelated donors for 91 patients (see breakdown of figures below):

- 475 requested for 91 patients
  - 314 received
  - 161 not received (34%)
    - 130 deleted
    - 31 temporarily unavailable
  - 256 UK VUDs requested (54%)

Transplant related activity
Of the 60 allogeneic transplants performed in 2014, 20 were from related sibling donors and 40 from unrelated donors. The majority of unrelated donors used were a full HLA match (10/10) and from the UK.

Unrelated donor HLA matching

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<td>11 (27.5%)</td>
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Unrelated donors used by registry

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<tr>
<td>UK</td>
<td>24 (60%)</td>
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<td>3 (7.5%)</td>
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<td>Sweden</td>
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</tr>
<tr>
<td>Portugal</td>
<td>1 (2.5%)</td>
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CMV and Blood Group matching
Of the 40 unrelated donors used, the CMV matching and blood group compatibility status is summarised below:

- 37/40 (92.5%) CMV matched
- 26/40 (65%) BGp matched
- 7/40 (17.5%) BGp compatible
- 26/40 (65%) BGp and CMV matched
NHSBT STEM CELL LABORATORY

Staffing
The Current Laboratory staffing equates to:
1 Band 8C = Laboratory Director
3 Band 7 = 2 Stem Cell Team Leaders, 1 Ovarian Tissue Team Leader
2 Band 6 = Specialist Biomedical Scientists
2 Band 5 = Biomedical Scientists
1 Student Intern*

In August 2014 an additional member of staff was recruited to facilitate the founding of a new Ovarian Tissue storage service.
*Student Interns are voluntary members of staff who can dictate their length of stay no greater than 12 months. Ovarian Tissue Team Leader is currently on a 2 year fixed term contract funded by the Steve Mills Fund, for the setup of the new service

Service Development
In 2014:

- Work was planned to facilitate the completion of vat room 3 which had remained incomplete after the initial work in 2013. The upgrade to the room to make the facility fully functional is expected to be completed by mid-spring 2015 and will allow all the liquid nitrogen tanks currently off-site to be repatriated to the Southampton centre in 2015.
- The ground work for a new Ovarian Tissue Service was instigated in 2014.
- NHSBT has an annual flow of Rapid Improvement Events (RIEs) designed to bring together national specialists and staff who undertake these tasks on a daily basis to be able to streamline the process and make them more efficient. In 2014 the areas targeted by these RIEs were; flow cytometry and dose counts, CFU assays and referral form.

Working links with UHS
The Steve Mills Stem cell Laboratory enjoys a strong working relationship with the transplant team at UHS this is facilitated by the calendar of meetings. Staff from both sides regularly attends:
- Twice weekly transplant planning meetings - one for autologous and one for allogeneic patients.
- Monthly joint operational and engraftment meeting – to discuss any operational issues and sign off the monthly engraftment data.
- Bi-monthly WBMT quality management programme meeting – the service has a regular agenda slot providing a report on any incidents, variances raised or pending and processing activity from the last meeting.

Processing
In 2014 the laboratory:
- Processed and cryopreserved 167 autologous HPC-A. These were stored in a total of 780 bags.
- Received 74 allogeneic HPC-A, 24 from sibling donors and 50 from volunteer unrelated donors. 5 allogeneic HPC-M were also received and 3 of these were from sibling donors.
- Processed and cryopreserved 62 Tc-T in 466 bags.
- Performed CD34 analysis on 298 peripheral blood samples.

Discards
98 Autologous HPC-A were discarded in 2014 a total of 388 bags. 4 HPC-M harvests were discarded a total of 17 bags. All collections came from a cohort of 62 patients
3 Allogeneic HPC-A harvests were discarded in 2014 in a total of 9 bags. 16 Tc-T harvests were discarded in a total of 83 bags all bags came from a cohort of 15 patients.

Claire Wiggins, Steve Mills Laboratory NHSBT Southampton
# 2014 Summary

## Transplant Patient Activity

<table>
<thead>
<tr>
<th>Referring Hospital</th>
<th>Allogeneic</th>
<th>Autologous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portsmouth</td>
<td>12</td>
<td>26</td>
</tr>
<tr>
<td>Southampton</td>
<td>11</td>
<td>20</td>
</tr>
<tr>
<td>IOW</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Bournemouth</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Poole</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Salisbury</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Basingstoke</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Chichester</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Dorchester</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Winchester</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Guernsey</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Jersey</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

**Allogeneic transplants** 60  
**Autologous transplants** 84  
**Total transplants** 144

### Stem cell source

<table>
<thead>
<tr>
<th>Stem cell source</th>
<th>Allogeneic</th>
<th>Autologous</th>
</tr>
</thead>
<tbody>
<tr>
<td>BM</td>
<td>4</td>
<td>(2 VUD &amp; 2 sib)</td>
</tr>
<tr>
<td>PBSC &amp; BM</td>
<td>1</td>
<td>(sib)</td>
</tr>
<tr>
<td>PBSC</td>
<td>139</td>
<td>(38 VUD; 17 sib; 84 auto)</td>
</tr>
</tbody>
</table>

### Allogeneic transplants: Donor type

- **Sibling** 20 (33.3%)
- **VUD** 40 (66.6%)
  - 28 = fully matched
  - 11 = 9/10 mismatched
  - 1 = 8/10 mismatched

### Disease indication – 1st transplant

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Allogeneic</th>
<th>Autologous</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Allogeneic</td>
<td>Autologous</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Referring Hospital</th>
<th>Allogeneic</th>
<th>Autologous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portsmouth</td>
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</tr>
<tr>
<td>IOW</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Bournemouth</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Poole</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Salisbury</td>
<td>5</td>
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</tr>
<tr>
<td>Basingstoke</td>
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</tr>
<tr>
<td>Chichester</td>
<td>3</td>
<td>5</td>
</tr>
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<td>Dorchester</td>
<td>1</td>
<td>1</td>
</tr>
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<td>Winchester</td>
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<tr>
<td>Guernsey</td>
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<td>6</td>
</tr>
<tr>
<td>Jersey</td>
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<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disease indication</th>
<th>Allogeneic</th>
<th>Autologous</th>
</tr>
</thead>
<tbody>
<tr>
<td>AML CR1</td>
<td>11</td>
<td>MM 42</td>
</tr>
<tr>
<td>AML CR2</td>
<td>4</td>
<td>Amyloid 3</td>
</tr>
<tr>
<td>AML REF</td>
<td>1</td>
<td>NHL 24</td>
</tr>
<tr>
<td>2\textsuperscript{nd} AML (4) or MDS (4)</td>
<td>8</td>
<td>HD 7</td>
</tr>
<tr>
<td>CMML</td>
<td>1</td>
<td>Germ cell 2</td>
</tr>
<tr>
<td>ALL</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Haemophagocytic lymphhistiocystosis</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>MM</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>MF</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>NHL (FL, T cell lymph)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>HD</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>SAA</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
ENGRAFTMENT

Each month engraftment data is presented, discussed and checked/signed off by a senior transplant consultant at the joint UHS NHSBT operational meeting held within the regular autologous planning meeting. Any anomalies with the results or data unavailable to present are discussed and if necessary, further investigated and brought back to the next meeting for final sign off.

2014 Engraftment

A total of 55 (92%) allogeneic transplant patients reached neutrophil engraftment in 2014 (within 21 days post transplant) with an average number of days; allogeneic = 17 and autologous = 13

<table>
<thead>
<tr>
<th>Allogeneic</th>
<th>Engraftment response not reached at 21 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplant</td>
<td>Total number = 60</td>
</tr>
<tr>
<td>Neut ≤0.5</td>
<td>5 (8%)</td>
</tr>
<tr>
<td>Platelet ≤20</td>
<td>8 (13%)</td>
</tr>
<tr>
<td>Platelet ≤50</td>
<td>14 (23%)</td>
</tr>
</tbody>
</table>

Comments
- 2 RIC VUD transplants had both delayed neutrophil and platelet response with 1 graft failure 1 low stem cell dose.
- 3 RIC VUD transplants had platelets ≤50 and were not reached before d100 with 1 ITU admission, a 2nd allograft with GvHD toxicity and 1 patient died 45 days post transplant.

<table>
<thead>
<tr>
<th>Autologous</th>
<th>Engraftment response not reached at 21 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transplant</td>
<td>Total number = 84</td>
</tr>
<tr>
<td>Neut ≤0.5</td>
<td>1</td>
</tr>
<tr>
<td>Platelet ≤20</td>
<td>15 (18%)</td>
</tr>
<tr>
<td>Platelet ≤50</td>
<td>30 (36%)</td>
</tr>
</tbody>
</table>

Comments
- Most late results were due to early discharge or before counts reached
- 3 patients not reaching platelets ≥50 at d100 post transplant were due to; poor mobilisation/stem cell dose, 2nd autograft and significant sepsis
- In addition, 1 patient had delayed platelets ≤50 (33 days) due to infection

Carol Hurlock, BMT Quality Programme Manager
DATA MANAGEMENT

Med A data collection – all transplant patients have data collection forms completed for their transplant, 100 day follow up and yearly follow up. The data is submitted to the EBMT Data Registry using the software, ProMiSe. In addition, an annual transplant activity form is submitted providing EBMT with overall numbers for transplant type/donor, stem cell source and disease indication for 1st transplants, additional transplants, DLI infusions and cellular therapies. In 2014 a total of 138 Med A forms for transplant up to 100 days were reported in ProMiSe reflecting the increased transplant patient activity within the WBMT service. Med A follow up forms are completed yearly for all allograft transplant patients and as many autograft transplants when information is provided by referring hospitals or patients are seen in Southampton.

In 2013 the BMT team began using a database; hospital integrated clinical support system (HICSS), to capture and record the transplant patient pathway from referral to discharge (death). As a team we are actively gathering, storing and analysing data for many purposes, both internal and external. Access to complete, accurate and timely data is essential and HICSS has provided us with the opportunity to do this efficiently in one database, using one record per patient procedure, reducing errors in data entry and duplication of data. Transplant patient data from January

In 2014 a retrospective review of all patients with stored stem cells was undertaken to facilitate appropriate and future storage. The NHSBT Steve Mills Laboratory was notified, in writing by the Consultant, of all deceased patients and any cells no longer viable for future use. This resulted in total storage saving costs of £56,883.54 and will continue to be regularly monitored to ensure appropriate storage and efficient savings.

The table below shows regular data management reporting

<table>
<thead>
<tr>
<th>REPORT</th>
<th>FREQUENCY</th>
<th>INTERNAL/EXTERNAL</th>
<th>PURPOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMT Activity</td>
<td>Monthly</td>
<td>INTERNAL</td>
<td>Used by finance for billing and clinical coding</td>
</tr>
<tr>
<td>Engraftment</td>
<td></td>
<td>INTERNAL</td>
<td>See previous page (15)</td>
</tr>
<tr>
<td>Quality Dashboard</td>
<td></td>
<td>EXTERNAL</td>
<td>Patient outcomes for commissioners and senior contracting managers</td>
</tr>
<tr>
<td>HTA Annual Activity Data</td>
<td></td>
<td>EXTERNAL</td>
<td>Activity data required to maintain licence</td>
</tr>
<tr>
<td>EBMT Activity Survey</td>
<td></td>
<td>EXTERNAL</td>
<td>Provides benchmarking for transplant activity across EBMT or specifically the UK (BSBMT)</td>
</tr>
</tbody>
</table>

Linda Jarvis, BMT Data Manager
RESEARCH

Medical staff within the BMT team actively contributes to research and development to further the field of transplantation and improve patient treatment and outcome.

In 2014, the department contributed to the following open trials:

- Targeted radiotherapy – phase I and II (multicentre)
- Clofarabine pre-conditioning (single centre)
- CMV Impact
- LenaRIC
- ProT4
- UKALL 14
- Maribavir Phase II
- EBMT/CIBMTR/BSBMT Registry Trials
- ITLC
- Orcharrd
- MMX
- MMXI

EDUCATION, TRAINING & COMPETENCY

Medical Staff
All medical staff are required to be trained and maintain competency appropriate to their role within the transplant team. All medical staff actively participates in the Quality Management Programme and are expected to read and acknowledge WBMT documents in Q-Pulse. In addition to undertaking Trust Statutory and Mandatory Training, Consultants in transplantation, the Associate Specialist, Transplant Fellow and Specialist Registrars undertake continuing education appropriate to their role within the transplant programme. Consultant competency is documented as part of the ongoing enhanced appraisal JACIE requirements. Specialist Registrars have a minimum of six months with transplant patients during their early and late training. Competency assessments for their transplant experience are completed which forms part of their training portfolio. Junior medical staff undertake an induction programme during their attachment. Transplant Clinicians organise a regular Specialist Registrar Training Day covering specific transplant topics. All individuals taking consent for stem cell harvest complete specific training as per HTA requirements.

Deborah Richardson, Consultant Haematologist

Nursing Staff
All senior nursing staff working within the BMT service are, at a minimum, educated to diploma/degree level, have experience in caring for cancer patients and attend the BMT specific training day that includes management of specific conditions common in patients undergoing transplantation. All of the senior transplant nurses have attended and passed history taking and physical assessment and support nurse led clinics. The Lead nurse is also a non medical prescriber, as is the senior ward manager, and Lead nurse for apheresis.

All ward based staff undergo training in administration of intravenous drugs, chemotherapy and will have the opportunity to attend further specialist courses in caring for patients undergoing autologous and allogeneic transplantation. Newly qualified staff complete a competency programme ensuring that they are able to work within cancer care and attend within this cancer care specific study days, complete competencies in drug administration and safe care of the patient prior to gaining further skills in intravenous drug administration and chemotherapy training. Due to the nature of the work undertaken, many staff have completed care of the highly dependent patient course, as well as masters modules in caring for haematology patients including blood and marrow transplantation.

All nursing staff undertake Trust Statutory and Mandatory Training, which includes safe blood transfusion training. Staff who have been trained in the return of cryopreserved stem cells will also
have completed a competency assessment. Staff on the ward and haematology day case areas provide nursing care for both transplant and non transplant haematology patients.

All nursing staff are expected to read and acknowledge WBMT documents in Q-Pulse according to their specific role/area of expertise and senior nursing staff actively participate in the Quality Management Programme.

In 2014, a new training programme was introduced for nurses wishing to train as advanced nurse practitioners. The two haematology/BMT ANPs are undergoing a specific training programme, which includes history taking and physical assessment, non medical prescribing, decision making and diagnosis, leading to an MSC in advanced clinical practice. To support this training programme an extensive competency document has been produced which also includes transplant specific competencies. The trainee ANPs are supported by a dedicated Consultant clinical supervisor as well as all the other medical staff on the unit.

In February there was an autologous study day that was well attended regionally. 6 nurses on C6 successfully completed competency assessment for autologous stem cell return to include defrosting of cryopreserved cells prior to infusion. There are now 10 ward staff trained and this will continue in 2015.

Senior BMT nursing staff attended the Wessex BMT Educational Forum meeting at Lainston House in November and individual staff achievements included Nikki McKeag nomination and appointment to the EBMT Education Committee and Sara Main attendance at the EBMT UK study day in November.

**Nikki McKeag, BMT Lead Nurse**