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SECTION A. GENERAL INFORMATION AND OVERVIEW

Programme:	South Wales Blood and Marrow Transplant Programme
Institution name:	Department of Haematology, University Hospital of Wales
ID:	1390
City:	Cardiff
Country:	United Kingdom
Type of inspection:	☒ Reaccreditation
Format of the Inspection:	☒On-site
Edition of standards used for inspection:	☒ 8th

Inspection date:	18/09/2025	Date of Inspection Report:	14/11/2025	Date of Summary Report: (for office use only)	08/01/2026

Certification Scope (mark as appropriate):					
AREA	PATIENT	HSCT		Immune Effector Cells	
		Allogeneic	Autologous	Allogeneic	Autologous
Clinical	Adult	☒	☒	☐	☒
	Paediatric	☐	☒	☐	☐
HPC, Marrow Collection	Adult	☒	☒		
	Paediatric	☐	☒		
HPC, Apheresis Collection		☒	☒		
Processing		☒	☒		

Directors (complete all sections):		
Facility	**Director**	**Medical Director**
Clinical (Adults)	Keith Wilson	-
Clinical (Paediatrics)	Phil Connor	-
Clinical Singleton (Adult)	Ann Benton	-
HPC (M) Collection	Wendy Ingram	Wendy Ingram
HPC (A) Collection	Jim Murray	Jim Murray
Cell Processing	Sarah Phillips	Keith Wilson

Inspectors & Observers:	
ADULTS	
Team Leader	Charles Crawley
Clinical – Adult Cardiff	Charles Crawley
Clinical – Adult Swansea	Paneesha Shankara
Marrow Collection	Charles Crawley
Apheresis Collection	Ilknur Kozanoglu
Donors	Ilknur Kozanoglu

Processing	Kay Carruthers
Quality Management - Cardiff	Songul Tepebasi
Quality Management - Swansea	Ruth Barrio Ortega
Clinical Adult Trainee	Damian Finnegan
PAEDIATRICS	
Team Leader	Birgitta Versluijs
Clinical	Birgitta Versluijs
Marrow Collection	Birgitta Versluijs
Apheresis Collection	Ilknur Kozanoglu
Ilknur Kozanoglu	Ilknur Kozanoglu
Processing	Kay Carruthers
Quality Management	Songul Tepebasi
Clinical Paediatric Trainee	Sanjay Tewari

Services provided to other facilities NOT inspected during this audit:
(Complete this where the inspector is aware of any other relationships with facilities not part of this application e.g. registries, other hospitals). If none, mark as N/A.

Outpatient clinic facilities at Llandough, this is about 6 miles from the University Hospital of Wales. The program provides outpatient clinic reviews only on this site. This facility was not visited but we reviewed a video tour of the clinical area and the facility is better suited to reducing the risk of nosocomial infection.

Observations on the interaction between clinical, collection and processing facilities:
(Reflect on what evidence you saw of interaction and communication between the different facilities)

Very integrated program with close and frequent interactions between all aspects of the programme

Distance between facilities:
(if possible, please describe the distance, duration and mode e.g 5km, 10min by car)

Collection Facility Adult to Clinical Unit SWBMT	5 minutes
Collection Facility Adult to Clinical Unit Singleton Hospital	1 hour
Collection Facility Paed to Clinical Unit SWBMT	5 minutes
Collection Facility Adult to Processing Facility	5 minutes
Collection Facility Paed to Processing Facility	5 minutes
Processing Facility to Clinical Unit SWBMT	5 minutes
Processing Facility to Clinical Unit Singleton Hospital	1 hour

Additional remarks:

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SECTION B. TEAM LEADER INSPECTION SUMMARY

Team Leader On-site Inspection Summary:
(Use this section to describe the inspection. Describe the overall impression of the programme. This point is sometimes called the "helicopter view" and means to consider all aspects together and not just as individual elements. The FACT-JACIE standards emphasize the total programme and the interactions in place between the different services. Each individual inspector should describe the facility(s) he/she has visited in their respective section of this report. Again, specific elements or deficiencies should be detailed in the Inspection Checklist).

The transplant program in Cardiff recently celebrated its 40th year and has transplanted over 3,000 patients. It has developed progressively over this time, expanding from sibling and autologous transplantation to include unrelated donors. A combined program was established with Singleton Hospital in Swansea (42 miles, approximately one hour away) in 2011. In 2019, the program initiated an IEC program with its first CAR-T patient, which was included in the scope of its accreditation at that time. The service is highly integrated, with a relatively stable and highly dedicated workforce.

Program leadership has been effective in ensuring that responsibilities are delegated to appropriate members of the team, resulting in clearly defined roles. The program benefits from this approach by making effective use of the skills of different team members, enabling them to play an active role in both the development and delivery of the service. This is reflected in the extensive use of advanced nurse practitioners, as well as in the integration of all team members—for example, the involvement of data managers in drafting transplant protocols prior to clinical review.

The program demonstrates a strong ethos of continuous improvement, reflected in an emphasis on research as well as service improvement. The main area of concern relates to the condition of the facilities, which is discussed below.

SECTION C. OBSERVATIONS

PERSONS INTERVIEWED DURING THE INSPECTION: *This section appears under the heading of each section (see below) and should be completed with the names and roles of the persons interviewed during the course of the inspection.*

MAIN STRENGTHS & AREAS FOR IMPROVEMENT: *This section appears below each section (see below) and describes the main strengths and areas for improvements e.g. well-trained team, excellent document management, need for more regular audits, etc.*

Cellular Therapy Product Administration & Clinical Facilities – ADULT - SWBMT	
Persons interviewed during the Inspection	
Position/role	**Name**
Programme Director	Keith Wilson
Transplant physician/Consultant/Specialist	Wendy Ingram
Transplant physician – IEC lead	Ceri Jones
Transplant physician	Jim Murray
Quality Manager	Nicola Davis
TYA Ward Manager	Sara Busby
B4 Ward Manager	Chelsie Goodwin
Clinical Practice Educator	Lisa James
Ambulatory Care Ward Manager (deputy)	Michelle Longmuir,
CART CNS	Emma John
Senior Nurse TYA	Bethan Ingram
Nurses in training (or newest nurse in the unit)	Olivia Jones
Pharmacist	Siobhan
Physiotherapist	Evelyn Evans
Psychologist	Kate Littler
Dietician	Juliet Morgan
Data Manager	Damith Nirmal
Data Manager	Mary Warren
Director of Estates and Facilities, Cardiff and Vale Health Board	Geoff Walsh
Deputy Director, NHS Capital, Estates, Welsh Government	Ian Gurney

Numbers of transplants for 12 months up to inspection date (Initial accreditations) or for previous accreditation cycle (Reaccreditations)
Please complete for the 12 months up to inspection date (Initial accreditations) or for the previous 4 years (Reaccreditations), being 1 the year/12 months prior to Inspection.

Year	Allogeneic	Autologous	CAR-T
2024	41	33	16
2023	42	47	19
2022	45	56	11
2021	41	48	6

Brief description of facility(s) inspected:
(Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist)

The main transplant ward is Ward B4, which comprises six single rooms and two double rooms. These rooms do not have ensuite facilities, and isolation is managed by providing a commode in the room, supplemented by shared toilet facilities. Commodes need to be emptied in the

dirty utility on the ward making an outbreak of C. dificle difficult to contain. The rooms are centrally HEPA-filtered but do not have a lobby. There is no provision for patients who may be infectious; these patients would need to be moved to the main haematology ward, which has two single rooms with neutral pressure.

The fact that the unit has not experienced significant nosocomial infections is a testament to the diligence of the staff in infection control rather than an indication of the adequacy of the facilities. The infrastructure is old and has not been refurbished at any time. Concerns were raised at previous inspections (2013 and 2019); however, there has been no progress in renovating the facilities.

The adjacent haematology ward has 15 beds and two side rooms (neutral pressure). The rooms are similarly of minimal size and lack ensuite facilities.

The outpatient unit is also old and tired, and there is concern that the state of maintenance may affect the ability to clean effectively. The waiting area is inadequate and represents an infection control risk. To mitigate this risk, fitter patients are followed up in an outpatient facility in Llandough, which is newer and of appropriate size and standard of repair.

Main Strengths & Areas for Improvement: *This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist*	
Strengths	– Highly effective and cohesive team. – High level of nurse-led delivery of care. Advanced nurse practitioners and clinical nurses deliver a large component of care. There are many examples of nurse-led clinics, and approximately two-thirds of post-transplant patient follow-up is undertaken by nursing staff, with around one-third undertaken by medical staff. – Exemplary pre-rehabilitation service. Pre-transplant assessment is conducted by a multidisciplinary team including physiotherapy, occupational therapy, dietetics, pharmacy, psychology, and clinical nurse specialists. This service has documented reductions in length of stay, increased speed of recovery, and associated cost savings. – Integral involvement of allied healthcare professionals. For example, data managers are involved in drafting transplant protocols, ensuring that data queries are resolved prior to admission, which has resulted in 100% EBMT data follow-up. – Excellent nurse training and use of policies and procedures, supported by a robust quality system.
Areas for improvement	<u>Inpatient Ward (Ward B4):</u> The main transplant ward, Ward B4, comprises six single rooms and two double rooms. These rooms do not have ensuite facilities, and isolation is managed by providing a commode in the room, supplemented by shared toilet facilities. Commodes need to be emptied in the dirty utility on the ward, making it difficult to contain an outbreak of C. difficile. The rooms are centrally HEPA-filtered but do not have a lobby. There is no provision for patients who may be infectious; such patients would need to be moved to the

	main haematology ward, which has two single rooms with neutral pressure. The unit has not experienced significant nosocomial infections; however, this reflects the diligence of staff in infection control rather than the adequacy of the facilities. The infrastructure is old and has not been refurbished beyond minimal updates, such as upgrading walls and floors for effective cleaning. Concerns were raised at previous inspections (2013 and 2019), but there has been no substantial progress in renovating the facilities. The adjacent haematology ward has 15 beds and two side rooms (neutral pressure). These rooms are similarly of minimal size and lack ensuite facilities. <u>Outpatient Unit:</u> The outpatient unit is old and tired. There is concern that the state of maintenance may affect the ability to clean effectively. The waiting area is inadequate and represents an infection control risk. To mitigate this, fitter patients are followed up in an outpatient facility in Llandough, which is newer and appropriately sized. <u>Major Issues:</u> The most serious concern is the state of the facilities. The inpatient unit poses an infection control risk, limits physical activity for patients in isolation, and does not adequately protect patient dignity. It is concerning that previous inspection findings have not been addressed. The day unit facilities are also of concern and are not fit for purpose. Most spaces have at least one additional chair beyond the capacity of the area. In the event that a patient deteriorates and requires resuscitation or intensive intervention, the evacuation of other patients in the room would be necessary. This applies to both the adult and Teenage Cancer Trust (patients aged 16–24) day units. The newer ambulatory unit is cramped. While one room is adequate, the remaining spaces are limited. The two-chaired room is too small for effective infection control. Additionally, there is an extra chair in the treatment area where the drug fridge is located, and medicines are prepared before administration. This arrangement compromises patient confidentiality and provides inadequate privacy for patients receiving treatment.

Cellular Therapy Product Administration & Clinical Facilities – PAEDIATRICS - SWBMT	
Persons interviewed during the Inspection	
Position/role	**Name**
Programme Director	Phil Connor
Transplant physician/Consultant/Specialist	Cathy Morley-Jacob
Physician in training	Celyn Kerry
Quality Manager	David Davis
Senior Nurse	Nicola Gilbert
Nurse ward manager	Sian Jones
Other BMT unit nurses	Jemma Smith
Pharmacist	Kerry Crompton
Intensive Care Lead	Siva Oruganti
Dietitian	Catherine Murray

Numbers of transplants for 12 months up to inspection date (Initial accreditations) or for previous accreditation cycle (Reaccreditations)
Please complete for the 12 months up to inspection date (Initial accreditations) or for the previous 4 years (Reaccreditations), being 1 the year/12 months prior to Inspection.

Year	Allogeneic	Autologous
2025	-	3
2024	-	2
2023	-	2
2022	-	3
2021	-	5

Brief description of facility(s) inspected:
(Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist)

The paediatric haematopoietic stem cell transplantation (HSCT) service is part of the South Wales Blood and Marrow Transplant (SWBMT) combined programme. The service is currently limited to autologous transplants, with both HSCT collection and administration carried out on Rainbow Ward, the dedicated haematology–oncology ward at Noah's Ark Children's Hospital for Wales (NACHW), within the University Hospital of Wales.

NACHW is a 120-bed inpatient facility encompassing all major paediatric subspecialties and an on-site Paediatric Intensive Care Unit. Rainbow Ward has 13 designated beds, with two cubicles specifically earmarked for autologous HSCT. There is a dedicated day care unit attached to Rainbow Ward and an outpatient department located one floor above the paediatric ward. At the time of inspection, the unit was fully staffed, with three beds closed to facilitate level 5 care for a young patient undergoing an autologous transplant, rather than due to nursing shortages. The service manages approximately 60–70 new paediatric malignancy cases per year.

The paediatric programme shares the SWBMT cell-processing facility. A dedicated Spectra Optia apheresis system is available for bedside collection of peripheral blood stem cells. Both an Advanced Practice Practitioner (APP), Nicola Gilbert, and the Paediatric Clinical Programme Director are certified and proficient in paediatric apheresis.

Following recent leadership changes, Dr Philip Connor is handing over the role of Clinical Programme Director to Dr Cathy Morley-Jacob.

Main Strengths & Areas for Improvement: *This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist*	
Strengths	– The programme benefits from being closely integrated with the larger South Wales Blood and Marrow Transplant (SWBMT) adult service, providing shared expertise and infrastructure. – The service is led by skilled and dedicated physicians and nurses, operating within a well-established paediatric haematology–oncology unit. – A robust quality management framework is embedded in the programme, ensuring consistency and safety in clinical practice. – Strong multidisciplinary collaboration is evident, with ready access to specialist input and paediatric intensive care support when required. – Clinical outcomes are excellent, with no transplant-related mortality reported and engraftment achieved within expected timeframes. – There is an excellent training and induction programme, with regular teaching for junior medical and nursing staff. – Nursing stability is notable, with minimal staff turnover contributing to continuity of care.
Areas for improvement	– The number of autologous HSCT procedures is below JACIE requirements. – There is excessive reliance on a single Advanced Practice Practitioner (APP) to deliver the service. The role would be strengthened by appointing a deputy and/or establishing closer collaboration with the adult apheresis team, thereby ensuring resilience and continuity. – Of the eight consultants on the on-call rota, only two currently fulfil the competencies required to lead the autologous HSCT programme. Ongoing training and competency development for the remaining consultants is essential if they are to continue contributing to HSCT care. – Further advancement in the digitalisation of medical records, planning documents, and the individual Excel sheets currently maintained by staff would streamline documentation, improve accessibility, and strengthen quality assurance. – Follow-up care for survivors could be strengthened, both in terms of the content and implementation of long-term screening guidelines. – A more structured and clearly defined transition pathway to adult services is required, supported by written documents and formal protocols to ensure continuity of care as patients grow older.

Cellular Therapy Product Administration & Clinical Facilities – Singleton (Adult- Auto)	
Persons interviewed during the Inspection	
Position/role	**Name**
Programme Director	Dr Ann Benton
Physician in training	Dr Rohini, Clinical fellow
Quality Manager	David Davies
Senior Nurse	Nia Roberts
Nurses in training (or newest nurse in the unit)	Not interviewed
Other BMT unit nurses	Sheeja Matthew Staff nurse
Pharmacist	Lauren Pitt
Intensive Care Lead	Not interviewed
Nurse Educator	Ann Jones

Numbers of transplants for 12 months up to inspection date (Initial accreditations) or for previous accreditation cycle (Reaccreditations)
Please complete for the 12 months up to inspection date (Initial accreditations) or for the previous 4 years (Reaccreditations), being 1 the year/12 months prior to Inspection.

Year	Allogeneic	Autologous
1	0	56
2	-	-
3	-	-
4	-	-

Brief description of facility(s) inspected:
(Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist)

The Autologous Transplant Service was established in 1997 and currently serves the local population of Swansea and Neath Port Talbot, as well as patients from the wider West Wales region on a sub-regional basis, including Cardiff. The Transplant Unit comprises four en-suite rooms and two step-down rooms.

The facilities are well maintained and suitable for autologous stem cell transplantation; however, the number of inpatient rooms needs to be increased to meet growing service demand. The outpatient area is clean, well-organised, and clearly signposted. High Dependency provision is also well supported and fully integrated within the service.

Main Strengths & Areas for Improvement: *This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist*	
Strengths	– Highly effective and cohesive team, well led by the local Programme Director. – Good co-ordination and communication between Cardiff and Singleton, with strong attendance at various transplant meetings. – The Autologous Transplant Service is delivering increased activity efficiently; however, expansion of space and workforce is needed to sustain and manage current demand effectively. – Committed team members consistently go beyond their duties to maintain a high standard of service. – Transplant outcomes are good.
Areas for improvement	– The Autologous Transplant Service needs to expand in both space and workforce to manage current demand. This expansion is vital to create capacity at Cardiff for delivering the expanding ICE therapy. – The Autologous Transplant Programme requires a robust succession plan for potential Programme Directors and BMT Nursing Coordinators. – The programme is heavily dependent on Sister Nia Roberts for smooth operation, highlighting the need for increased resilience. – Expansion of nursing roles at Singleton is needed, in line with the role expansion at Cardiff. – The Nurse Educator role needs to be restructured to enable the post holder to deliver more effective transplant training to the nursing team. – Current pharmacy capacity is sufficient for existing activity; however, additional staff will be required if activity increases, as observed over the past two years. – The pharmacist requires dedicated time for transplant-related Continuing Professional Development (CPD).

HPC, Marrow Collection Adult & Paed - SWBMT	
Persons interviewed during the Inspection	
Position/role	**Name**
Physician who performs harvests	Wendy Ingram
Educational Lead Peri-Op services	Babs Jones
Dept Processing Facility Director	Serdar Killicer

Numbers of marrow collections for 12 months up to inspection date (Initial accreditations) or for previous accreditation cycle (Reaccreditations)
Please complete for the 12 months up to inspection date (Initial accreditations) or for the previous 4 years (Reaccreditations), being 1 the year/12 months prior to Inspection.

Year	Adult		Paediatrics	
	Allogeneic	Autologous	Allogeneic	Autologous
2025	-	1	-	-
2024	1	-	-	1
2023	-	-	-	-
2022	-	-	-	-
2021	-	-	-	-

Brief description of facility(s) inspected:
(Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist)

Bone Marrow Harvest (BMH) procedures are undertaken in the main operating theatres for adults and in the paediatric theatres for children. These provide a suitable environment and are well maintained, including thorough cleaning.

There is extensive, well-documented training of theatre staff, with appropriate storage of equipment and materials. The paediatric theatre was not directly reviewed but is managed and staffed by the same peri-operative services team. BMH procedures are infrequent; therefore, prior to every procedure, a joint training session is conducted to ensure that haematology staff are aware of and compliant with theatre policies and procedures, and theatre staff are aware of and compliant with haematology- and BMH-specific procedures.

Procedures are performed by a competent haematology or paediatric haematology consultant, supported by a second consultant or trainee.

The processing facility is involved in the collection procedure, being responsible for tracking the volume collected, ensuring the integrity of the collection, and filtering the product.

Main Strengths & Areas for Improvement:
This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist

Strengths	Well-established pathway with effective communication and interaction between theatre staff and the haematology (BMH) team.
Areas for improvement	Activity levels are below the minimum threshold and need to be addressed. The team should consider establishing competency criteria for BMH and monitor team members against these criteria.

HPC, Apheresis Collection Adult & Paed - SWBMT	
Persons interviewed during the Inspection	
Position/role	**Name**
Collection facility director	Jim Murray Phil Connor (paediatric)
Collection facility medical director	Jim Murray Phil Connor (paediatric)
Staff involved in collections of cells (nurse, technician)	Jen Rose Holly Morgan Nicola Gilbert (paediatric nurse)
Quality Manager	Nicola Davis

Numbers of apheresis collections for 12 months up to inspection date (Initial accreditations) or for previous accreditation cycle (Reaccreditations)
Please complete for the 12 months up to inspection date (Initial accreditations) or for the previous 4 years (Reaccreditations), being 1 the year/12 months prior to Inspection.

Year	Adult		Paediatrics	
	Allogeneic	Autologous	Allogeneic	Autologous
1	41	48	-	5
2	45	56	-	3
3	42	47	-	2
4	41	33	-	4

Brief description of facility(s) inspected:
(Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist)

Adult apheresis unit,
Paediatric clinic,
Paediatric apheresis unit,
Processing Unit

Main Strengths & Areas for Improvement:
This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist

Strengths	Adult Apheresis Unit: The Adult Apheresis Unit demonstrates exceptionally high standards of practice, with a cohesive, well-trained team delivering safe and efficient procedures. Overall coordination between nursing, medical, and laboratory teams ensures seamless patient management and traceability throughout the process. The unit operates under a mature quality management system, with excellent adherence to SOPs, documentation standards, and validation procedures. Internal audits and training records reflect a strong commitment to maintaining compliance with JACIE standards. There is clear evidence of structured staff training and competence assessment. Staff demonstrate a high level of awareness regarding donor safety, product integrity, and equipment qualification. Continuous education and retraining activities are well-documented and actively maintained. Communication with clinical teams, collection scheduling, and coordination with processing and laboratory units are exemplary.

	Feedback mechanisms are in place, and interdepartmental collaboration contributes significantly to the overall quality and safety of the programme. Paediatric Apheresis Unit: The Paediatric Apheresis Unit is staffed by an experienced and highly dedicated team, with a strong commitment to patient safety and individualized care. The environment is child-friendly and well-adapted to the specific needs of paediatric patients, providing a reassuring and supportive atmosphere for both patients and families. Communication between nursing, medical, and laboratory teams is effective, ensuring coordination of care and appropriate management of paediatric collections. Staff demonstrate a compassionate approach, with particular attention to patient comfort and procedural safety.
Areas for improvement	Adult Apheresis Unit: While the Adult Apheresis Unit demonstrates high-quality practice and excellent teamwork, several areas for improvement have been identified: – Documentation of Point-of-Care Testing: Point-of-care tests are performed for all patients and donors prior to procedures (including COVID-19 testing). However, test results are not formally recorded, and the process lacks full traceability. Implementation of proper documentation and record retention is recommended. – Physical Space Expansion: The current layout of the apheresis area is functional but limited. Expansion of the physical space would enhance workflow efficiency, privacy, and safety, particularly during simultaneous procedures. – Product Labelling: The apheresis team should take a more active role in the labelling process of cellular therapy products to ensure consistency and alignment with quality and traceability requirements. – ISBT-128 Compliance: Current labels are not compliant with ISBT-128 standards. Transitioning to ISBT-128-compliant labelling is strongly recommended to support harmonization, interoperability, and regulatory compliance. Paediatric Apheresis Unit: Although the Paediatric Apheresis Unit maintains high professional and ethical standards, several areas require attention to achieve full compliance with JACIE standards: – Low Collection Activity: The number of paediatric apheresis procedures performed is limited, which may impact ongoing competency assessment and validation of processes. Periodic simulation or shared practice with the adult unit could help maintain proficiency.

	– Validation and Documentation: Some validation and revalidation records for paediatric-specific procedures are incomplete or not clearly documented. A systematic approach to validation, including defined acceptance criteria and traceable documentation, should be implemented. – Staff Competence and Training Records: Training documentation specific to paediatric collections is limited. Establishing structured training and competency assessment tailored to paediatric practice would strengthen compliance. – Labelling and Identification: Some storage areas and materials within the unit are not labelled, which may affect traceability. Consistent labelling and identification of all materials should be ensured.

Cellular Therapy Product Processing - SWBMT	
Persons interviewed during the Inspection	
Position/role	**Name**
Dept. Processing Facility Director	Sedar Killicer

Numbers of components processed for 12 months up to inspection date (Initial accreditations) or for previous accreditation cycle (Reaccreditations)
Please complete for the 12 months up to inspection date (Initial accreditations) or for the previous 4 years (Reaccreditations), being 1 the year/12 months prior to Inspection.

Year	Allogeneic	Autologous
1- 19.09.2024-18.09.2025	52	160 + 18 CART
2 - 19.09.2023-18.09.2024	45	154 + 13 CART
3 - 19.09.2022-18.09.2023	47	169 +13 CART
4 - 19.09.2021-18.09.2022	53	139 + 15 CART

Brief description of facility(s) inspected:
(Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist)

During the inspection, the following units were visited:

1. Blood Transfusion
2. Flow Cytometry
3. Cellular Therapies Processing Laboratory
4. Cellular Therapies Cryostorage

The Cellular Therapies service operates from the same location as Integrated Laboratory Medicine, fostering a close and collaborative relationship with the Blood Transfusion and Flow Cytometry teams.

Main Strengths & Areas for Improvement:
This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist

Strengths	– The Processing Facility is run by highly experienced and dedicated staff members. – The Processing Facility team is fully integrated with clinical teams, staff, and services, resulting in a highly cohesive service. – The Processing Facility maintains close working relationships with the Integrated Laboratory Medicine services, enabling them to utilise the expertise of the Blood Transfusion and Immunology Services.
Areas for improvement	<u>1.Facilities:</u> The Cell Processing Facility is aging. While it remains functional and adequate for the current workload, there are clear design and infrastructure limitations. For example, the Grade B change area opens into an unclassified area, and there are no locker or

	changing facilities for staff to prepare appropriately for gowning into the cleanroom space. The cleanroom itself is small and can only accommodate one cabinet. During the inspection, it was noted that the laboratory had recently acquired two additional rooms/spaces for expansion; however, these are not currently fitted to meet the needs of the processing facility. Consideration should be given to the level of investment required to future-proof the existing environment, and investment should also be considered to make the two newly acquired spaces fit for purpose. <u>2. Staffing:</u> Staffing levels in the processing facility are inadequate. Retention issues were discussed and noted as a problem for the team. The Deputy Processing Facility Director is currently undertaking an active role in cleanroom processing and ancillary tasks on a regular basis to cover staff shortages. Consideration should be given to recruitment to restore appropriate staff levels. Strategies to encourage career progression should also be explored to increase staff retention. <u>3. On-Call:</u> The department does not operate an official on-call rota and relies on the goodwill of existing staff to respond to alarms for liquid nitrogen vessels, fridges, and freezers. Given current staffing levels, this can result in one or two staff members being entirely responsible for responding to alarms. This arrangement is not reliable, lacks structure, and does not provide a standardised response to different alarms, with some alarms not being addressed until the following day. A fully funded and well-manned on-call rota is required for the response to liquid nitrogen systems. The absence of such a rota poses significant concerns for: *A. Health and Safety:* Staff in surrounding areas may attempt to respond to an alarm out of hours without fully understanding the risk of asphyxiation associated with liquid nitrogen complications. *B. Patient Pathway:* Each liquid nitrogen vessel contains irreplaceable patient products. Failure to respond appropriately to an alarm could, in severe circumstances, result in the complete loss of all products within that vessel. While the department has demonstrated that substantial control measures are in place to avoid catastrophic failures, a more robust response to all out-of-hours alarms is required. <u>4. Labelling:</u> During the inspection, the department confirmed that Stemsoft is in the final stages of validation and provided evidence that the new system will fully comply with JACIE 8.1 standards. However, at the time of inspection, this system was not yet in use. Labelling remains an identified area for improvement, though it is acknowledged that this issue is actively being addressed and rollout is imminent.

CM7, C7 & D7 Labels (Cell Collection & Cell Processing)	
Inspector who performed check	
Area	**Name**
HPC Marrow Collection Labels	Charles Crawley and Birgitta Versluijs
HPC Apheresis Labels	Ilknur Kozanoglu
Processing Labels	Kay Carruthers

Quality Management SWBMT	
Persons interviewed during the Inspection	
Position/role	**Name**
Physician	Wendy Ingram, Cathy Morley
Technician	Serdar Killicer,
Nurse	Kerenza Moulton, Nicola Gilbert
Quality Manager	Nicola Davies
Dept Processing Facility Director	Serdar Killicer,

List of facility(s) visited:
List the facilities visited in this visit as part of the Quality Management system

During the inspection, the following units were visited:

- The Cell Processing Unit
- The Adult Apheresis Unit
- The Paediatric Clinic
- The Paediatric Apheresis Unit

Main Strengths & Areas for Improvement: *This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist*	
Strengths	– The transplant centre comprises adult and paediatric clinics, bone marrow collection, adult and paediatric apheresis units, and a cell processing laboratory, all located on the same campus in close proximity. – The cell processing laboratory is immediately adjacent to the adult apheresis unit, while the paediatric apheresis unit is located within the paediatric clinic unit. This arrangement facilitates rapid and coordinated delivery of patient care, including the transfer of cells and samples. – The staff are highly experienced and demonstrate a high level of skill in their work. During the inspection, it was evident that, despite the centre operating with older infrastructure, all procedures were implemented with dedication, care, and motivation. – All processes comply with legal and regulatory requirements. – Long-serving staff contribute to strong teamwork, cooperation, and stability. – The Clinic Director's commitment to improving the quality management system is clearly observed.
Areas for improvement	– Current job descriptions lack basic elements, including the details of the individuals who prepared and approved them, form numbers, and dates.

	– Competency assessments for critical procedures have not been carried out annually, and some important audits have not been performed. – There are no specific procedures in the relevant SOPs for elderly, extremely thin, or obese donors. Furthermore, there are no clear definitions regarding the use of blood and blood products by donors. – Significant deficiencies exist in processes demonstrating the effectiveness of quality management in the Bone Marrow Collection Unit, including stock management, staff training, disaster plans, and the storage of short-term cellular therapy products.

Quality Management Singleton (Adult- Auto)	
Persons interviewed during the Inspection	
Position/role	**Name**
Physician	Dr. Ann Benton
Nurse	Nia Roberts and Amy Saunders (senior nurses) Zvinaiye Shenje and Anne Jones
Quality Manager	David Davies

List of facility(s) visited:
List the facilities visited in this visit as part of the Quality Management system

During the inspection, the following units were visited:
- Transplant Clinic Unit
- Intensive Care Unit

Main Strengths & Areas for Improvement: *This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist*	
Strengths	– Despite a significant increase in activity and the number of transplants, the team continues to achieve good outcomes. – This success is largely attributable to the commitment and dedication of all team members, which is also reflected in the positive feedback received from patients.
Areas for improvement	– Staff training is currently conducted during their spare time, whereas it should ideally take place during working hours. – Additional personnel are required to adequately sustain the current level of activity. – A robust succession plan should be developed for both the Senior Nurse and the Transplant Physician. – Notable differences exist between the two transplant programmes. For example, at Singleton Hospital, patients do not have access to pre-rehabilitation or rehabilitation services, leading to inequities in patient care. – Professionals without access to Q-Pulse are unable to view updates to the system. It is necessary to improve the process for informing staff about SOP updates and to monitor whether professionals have read and understood them. For critical changes, an SOP is already in place to provide training and to record both the training and confirmation of SOP review.

SEE INSPECTION CHECKLIST FOR DETAILS OF OBSERVATIONS

1 SECTION D: ACCREDITATION COMMITTEE SUMMARY

The Committee has endorsed the observations made during this inspection which are detailed in this report and which should be responded to by the applicant. Overall assessment:

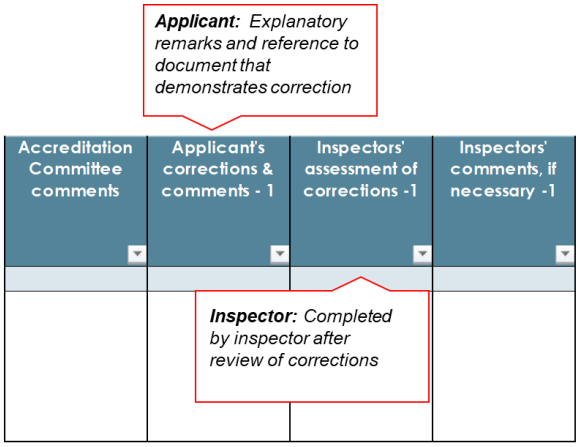
Significant deficiency or deficiencies documented at the site inspection. The JACIE Accreditation Committee will determine the adequacy of the facility's response and pronounce upon accreditation based on the Programme Director's documented correction of all deficiencies and satisfactory response to recommendations

Conditions: Complete where any conditions are attached to the eventual accreditation e.g. laboratory accreditation limited to service provided to a specific hospital
Your Centre does not meet the accreditation requirements for Bone Marrow paediatric activity as defined by the Standards (see Std. CM1.5) therefore, at this stage, the Accreditation Committee is unable to grant accreditation for Bone marrow collection. The options to move forward will be (a) to reach BM activity requirements by the time you submit the Evidence of corrections or (b) to remove the BM Collection from the scope of your accreditation, in which case the rest of the areas can be accredited as soon as the deficiencies are corrected. Your Centre does not meet the accreditation requirements for Paediatric activity as defined by the Standards (see Std. B1.5) therefore, at this stage, the Accreditation Committee is unable to grant accreditation for Clinical Paediatric Unit. The options to move forward will be (a) to reach BM activity requirements by the time you submit the Evidence of corrections or (b) to remove the BM Collection from the scope of your accreditation, in which case the rest of the areas can be accredited as soon as the deficiencies are corrected
Date for submission of evidence of corrections:
6 months from receipt of this report
Additional Comments:
Click or tap here to enter text.
General issues arising from this inspection:
Click or tap here to enter text.

General Directions Given to Programmes for Correcting Cited Deficiencies:

Where issues have been identified (as Non compliances or Partially compliances in the Checklist), the following steps must be completed:

1. You must document in writing how your programme has corrected each of the deficiencies. Correction of deficiencies may take the form of a new protocol or procedure, a revised protocol or procedure, new forms developed and put into use, new staff, new training processes, etc. Enter this information into the corresponding section of the Inspection Checklist aligning the corrections information with the remarks of the inspector and/or the Accreditation Committee (see image).



2. Labels: corrections to labels should be detailed in a separate document. This could be a simple Word document. Entitle this document as “Labelling response and corrections” and refer to the type of label which has been corrected or amended. For example, “C7.5.1 Apheresis label at completion of collection”.

3. Your documentation of correction of each deficiency must include a description of how your programme will comply with the citation and copies of any policies, procedures, protocols or documents that demonstrate the corrective action has been implemented

4. Please indicate as new or show clearly any changes in policies, protocols or procedures so that reviewers can easily understand your corrections and changes

5. If there are any long-term solutions to deficiencies, such as new construction being required to provide adequate space, the plans for such corrections should be included with your response, although the actual construction is not required to have been completed. Please include as much detail as possible.

6. Where the summary reports state “It is unclear that...” or “There is no evidence that...”, you should submit the evidence (such as a policy, protocol, procedure or an audit report) that the practice at your facility is already in compliance, or that you have made the necessary changes to ensure compliance.

7. Please organise your response according to the deficiencies as stated in the enclosed summary report, and be as clear as possible in your responses. Highlight specific sections of procedures or protocols that you wish to call to our attention.

8. Review our designation of the facilities you wish to have accredited for each of the services your programme provides. If any facility designation is incorrect, please notify in writing of the correct designations as soon as possible. Also, include any significant staff changes that have occurred since your submission.

9. Your complete response is expected within the timeframe indicate in Section D - Date for submission of evidence of corrections.

10. If you disagree with any of the findings of the on-site inspection team or the reviewers, submit a written statement outlining the reasons that you disagree, along with as much documentation as possible to support your opinion to the Accreditation Coordinator.

11. Your response should be uploaded in SharePoint as per JACIE Office instructions and a notification be sent to the JACIE Accreditation Office where your response will be evaluated. If the response is determined to be satisfactory, accreditation will be awarded for the services and facilities as described above. If any questions remain after our review, these will be submitted to the JACIE Accreditation Committee for final determination.

Note: The applicant should also refer to the Inspection Checklist for specific deficiencies where these have been observed during the inspection.