S(P)EAR COMMITTEE ANNUAL REPORT 2015

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Report

The committee received and considered 89 reports during 2015 (compared to 92 in 2014).

Donor SEARs

Sixty-two (63) donor SEAR reports were considered.

Ten (10) reports were after HPC Marrow harvest and 5 after HPC Apheresis collections.

Malignancy

Twenty-six (26) malignancies were reported, all more than a year after donation except for a testicular seminoma 4 weeks after HPC apheresis donation, breast cancer 4 months after HPC apheresis donation and a glioblastoma 6 months after apheresis collection. A single occurrence of breast cancer 4 years and 3 other melanomas occurred after HPC Marrow harvest, all were after HPC Apheresis collection

Site of malignancy	**n (time after donation)**
Melanoma:	6 (1-4yr, median 2y)
Breast	5 (4mo-7y, median 5y))
Renal :	2 (4y, 7.5y)
Seminoma:	2 (4 wk, 1.5 y)
Bile duct	1 (2y)
Bladder	1 (5y)
Cervix	1 (7y)
Dermatofibrosarcoma :	1 (2.5y)
Gastric	1 (1y)
Glioblastoma	1 (6mo)
Pancreas	1 (3y)
Prostate	1 (5y)
Spinal cord tumour	1 (5y)
Thyroid	1 (4y)
Acute lymphoblastic leukaemia	1 (2y)

The imputability of all malignancies was finally coded as **unlikely** by the committee except for the seminoma at 4 weeks which was **excluded** as it was presumably present prior to harvest and one breast cancer developing 4 years after HPC marrow collection which was **excluded** based on no conceivable link between donation and the malignancy.

Autoimmune disorders

Thirteen (13) reports are included in this category, although it is uncertain whether any or all of them were true autoimmune disorders

Multiple sclerosis	4 (during collection, 2y, 6y, 13y)
Inflammatory bowel disease	3 (1.5y, 3y, 7y)
Alopecia areata	1 (8y)
"Chronic Lyme disease"	1 (2mo)
Grave Disease	1 (7 mo)
Hypothyroidism	1 (9y)
Pernicious anaemia	1 (3y)
Seronegative arthritis	1 (6y)

Other Donor SEAR

Twenty (20) other Donor SEARs were reported.

1 report in which a transplant was cancelled due to patient relapse but collection centre not informed was determined to be a communication failure and **not** a SEAR. (in this case the product was still collected and then cryopreserved at the TC).

6 Infection-related

- Pneumonia (during HPC Apheresis collection)
- Endocarditis (6mo after HPC Apheresis collection)
- Encephalomyelitis (2y after BM harvest)
- Osteomyelitis (60d after HPC Marrow collection)
- Acute CMV infection (2d post HPC Apheresis collection)
  - Same donor also experienced lymphocytic meningitis (4mo post)

1 Anaemia (unspecified, 1y post HPC Marrow collection)
1 Polyarthritis (during mobilisation)
1 Tetany (during apheresis)
1 Pain (immediately after HPC Marrow collection)
1 Hypotension (during HPC Apheresis collection)
1 Bradycardia (during HPC Marrow collection
1 Vertigo (2mo post HPC Apheresis collection)
1 Chronic inflammatory polyneuropathy (3y post HPC Apheresis collection)
1 Polymyalgia (6mo after HOC Apheresis collection)
1 Transient Ischaemic Attack (8d post HPC Apheresis collection)
1 Macroscopic haematuria (during mobilisation)
1 Erythema nodosum (1y post HPC Apheresis collection)
1 Incorrect post-collection transfusion to donor

Assessment of imputability (Donor SEAR)

The committee assessed each reported for causation. This service is designed to be advisory to the reporting registry.

The committee agreed with the assessment of the reporting registry for 47 (of 63) reports as to imputability.

7 reports were upgraded (e.g. unlikely to definite or probable to definite)

9 reports were downgraded (e.g. definite to probable or probable to possible)

In each category, after classification by the committee

Definite	7
Probable	4
Possible	8
Unlikely	39
Excluded	4
Not assessable	1

The four excluded cases included the one noted above as a communication issue (originally coded as **Definite** by the reporting registry), and the case of the seminoma at 4 weeks which was originally coded as **Unlikely**. The other excluded cases (also coded as excluded by the reporting registries) were the cases of encephalomyelitis and breast cancer after HPC marrow collection. One case classified as **Not Assessable** by the registry and reclassified to **Unlikely** by the committee was a case of colitis developing 1.5 years after HPC Apheresis collection. The committee generally assigns cases of autoimmune phenomena occurring late after growth factor administration as unlikely.

The case of haematuria during mobilised was reclassified as **Definite** (from **Probable**) given that it occurred during growth factor administration and settled later. (This was felt to be a likely case of pre-existing subclinical IgA nephropathy exacerbated by growth factor administration). Two cases of melanoma occurring in donors after HPC Marrow collection were reclassified to **Excluded** from **Unlikely**.

One report classified as **Definite** by the committee was originally reported as a Product SEAR where the donor was administered a unit of homologous rather than autologous blood.

Patient SEAR

Three patient SEAR events were reported (15 in 2014).

1 Systemic Inflammatory Response after infusion of HPA Apheresis product requiring paediatric intensive care admission. This was upgraded from **Possible** to **Probable**.

1 episode of cardiogeneic shock following acute myocardial infarction (which was described as not-unexpected). It was upgraded from **Unlikely** to **Possible**.

1 episode of hypertension, hypoxia, tachypnoea and chest pain following a cord blood infusion where the event was assessed as **Probable** both by the reporter and the committee.

Product SPEARs

Fifteen (15) product-related incidents were reported. Seven (75) reports were for HPC Apheresis products, and 4 each for HPC Marrow and HPC Cord products.

Of the HPC Cord reports, 3 reports were of a cracked and/or leaking bag. These were all reclassified as **Excluded** as no impact on the patient resulted (other products were made available). The fourth report was of a lower than expected CD34 count in the product classified as **Excluded** as there was no impact on the patient.

Of the 7 reports of HPC apheresis products, one was reclassified to **Excluded** from **Not Assessable**. This was a report of an inadequate cell count in the first collection and a clotted second collection but then the discovery of there actually being adequate numbers of cells in the first unit and transplant proceeded with that unit. Another was **Not assessable** as it was a report of a collection centre not diluting a unit to the transplant centre's prescription, One was **Excluded** as it was a report of a minor cell count discrepancy. Another **Excluded** collection was after the report of a fibrin strand in the collection which was successfully removed by filtration. One was classified as **Definite** as the product label contained to donor's full name. Three were classified as **Possible** due to positive bacterial culture of the product or donor with no patient consequence.

Of the four (4) HPC Marrow reports, 3 had clots in the bag and were not reclassified, and one was of a contaminated product with **possible** transmission of the bacterial infection to patient.

Transport Issues

Eight (8) transport-related events were reported:

1. Temperature curve out of range (assessed to be due to an out-of-date model of temp recorder). **Excluded**
2. Prolonged transport (55 and 64 hrs) by commercial courier (two reports, both to Australia, resulted in corrective action in the form of reaccreditation of courier companies). **Definite**
3. Product stolen on a train during transport. **Not assessable**
4. Outer Bag damaged in transit. **Not assessable**
5. Crack in bag. Alternative product required. **Definite**.
6. Two instances of product arriving thawed. Both assessed as **Possible**.