S(P)EAR COMMITTEE ANNUAL REPORT 2014

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Report

The committee received and considered 92 reports during 2014.

Donor SEARs

Fifty (50) donor SEAR reports were considered. They were received from 16 registries in 15 countries.

Nine (9) reports were after HPC Marrow harvest and 41 after HPC Apheresis collections. Thirty (30) affected donors were male, 18 female and two had no sex recorded.

Malignancy

Sixteen (16) malignancies were reported, all more than a year after donation except for a metastatic colorectal cancer 5 months after HPC Marrow harvest and one testis cancer.

Testicular cancer:	3
Oral cavity cancer:	2
Acute leukaemia:	2
JAK2 mutated Polycythemia Vera:	1
Assorted solid tumours:	8

Autoimmune disorders

Four (4) reports, all > 1yr post donation

Seronegative polyarthritis, polymyalgia, polyneuropathy and ulcerative colitis

Other reports

Thirty (30) other SEARs were reported.

7 Allergy related.

4 Cardiac related.

3 Gastro intestinal related.

2 Infection related.

2 Pulmonary related.

12 other.

Assessment of imputability

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 33 reports as to imputability.

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

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

1 awaits further information before assessment

Patient SPEAR

Fifteen (15) patient SEAR events were reported.

2 cytogenetic abnormalities in donor cells in the recipient.

10 fever/respiratory distress/hypotension/chest pain.

1 donation changed to HPC Marrow after commencing mobilisation due to fever in donor and no further administration of growth factor

1 patient seizure.

1 episode of incorrect reporting of the donors' cytomegalovirus CMV serostatus.

Assessment of imputability

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 8 reports as to imputability.

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

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

Product SPEARs

Twenty-eight (28) product-related incidents were reported.

9 related to a leak or damage to bag.

8 related to lower than expected cell counts.

3 due to a labelling error.

2 wrong cell count/dilution (administrative/technical) mistakes.

6 other

Assessment of imputability

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 15 reports as to imputability.

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

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

2 await further information before assessment

Transport Issues

Eight (8) transport-related events were reported with one or more instances of the following:

Delayed arrival of one of two cord blood units.

Sample bag empty of contents on arrival at the transplant center.

Customs delays.

Delayed shipping.

Thawed cord blood unit received.

Temperature monitoring issues with product.

Product irradiated at an airport.

Assessment of imputability

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 4 reports as to imputability.

1 was upgraded (e.g. unlikely to definite or probable to definite)

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

1 awaits further information before assessment