	Title: S(P)EAR annual report 2016			
	Document type	Annual Report	WG/Committee	SEAR
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S(P)EAR COMMITTEE ANNUAL REPORT 2016

Members of committee: Jeff Szer, Bronwen Shaw, William Huang, Thilo Mengling, Matti Korhonen, Jerry Stein, Heidi Elmoazzen, Mirjam Fechter, Liz O’Flaherty, John Miller, Jeremy Chapman, Brian Lindberg, Lydia Foeken, Monique Jöris

Report


The committee received and considered 254 reports during 2016, compared to 89 in 2015. They were received from 26 organisations in 20 countries.

Donor SEARs

Two hundred and three (203) donor SEAR reports were considered. After evaluation 3 reports were considered as non-reports. Thirty-two (32) incidents occurred after HPC Marrow harvest, 165 after HPC Apheresis collections, 4 after MNC-Apheresis collections, 1 after HPC-Cord collection and 1 after DLI collection. One hundred and twenty-seven (127) affected donors were male, 73 female and 3 had no sex recorded.

Malignancy

Type	N	Time after donation in months [median (range)]
Breast cancer	9	48 (6 – 132)
Haematological malignancies*	8	30 (11 – 60)
Testicular cancer	5	36 (24 – 56)
Gastrointestinal cancer	4	50 (24 – 60)
Basalioma	4	15 (1 – 24)
Melanoma	4	46 (36 – 78)
Cervical cancer	2	30
Prostate cancer	2	25 (1 – 48)
Thyroid cancer	2	30 (24 – 36)

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Renal cancer 2 25 (1 – 48)

Other^ 6 36 (8 – 60)

Total 48

*Haematological malignancies include 1 AML, 2 B-cell Lymphomas, 1 essential thrombocytosis, 2 NHL and 2 Non-Hodgkin. ^Other malignancies include 1 urothelium carcinoma, 1 ovarian cancer, 1 rectal cancer, 1 brain tumour and 1 Ewing’s sarcoma.

Autoimmune disorders

Type	N	Time after donation in months [median (range)]
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Ulcerative Colitis	8	6 (2 – 30) 3 unk
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Rheumatoid Arthritis	6	24 (10 – 92)
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Multiple Sclerosis	6	6 (4 – 15) 3 unk
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Ankylosing Sponditis	5	24 (6 – 41)
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Crohn’s Disease	4	36 (25 – 60)
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Grave’s Disease	3	Unk
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Psoriatic Arthritis	3	57 (30 – 84)
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Diabetes Mellitus type 1	2	84 (36 – 132)
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Spondylarthritis	2	33 (18 – 48)
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Other*	8	21 (1 – 65)
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Total 47


*Other immune disorders include 1 autoimmune colitis, 1 autoimmune connective tissue disorder, 1 alopecia areata, 1 chronic sarcoidosis, 1 lichen sclerosis, 1 lymphocytic colitis, 1 polymyalgia rheumatic and 1 reiter’s syndrome.

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Other reports

Type	N	During mobilisation N	During collection N	After donation N (range)*
Infection	17	1		16 (1 D – 48 M)
Cardiovascular	14	3	5	6 (1 D – 21 M)
Central Nervous System	12			12 (1 D – 13 M)
Peripheral Nervous System	10	1		9 (3 D – 12 M)
Haematological	7	1	1	5 (6 D – 8 M)
Gastro intestinal	3	2		1 (1 D)
Pulmonary	3		1	2 (1 D)
Allergy	3	2	1	
Social/psychological	3			3 (12 M – 48 M)
Renal	2			2 (2 D)
Other	34	8	2	24 (1 D – 36 M)
Total	108			

*D: days, W: weeks, M: months.


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Assessment of imputability

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

Reported imputability	N	Assessed imputability	N	Imputability changed	N
Definite	21	Definite	25	Agreed	137
Probable	22	Probable	17	Upgraded*	23
Possible	40	Possible	26	Downgraded^	18
Unlikely	112	Unlikely	105	To excluded	24
Excluded	6	Excluded	29	To not assessable	1
Not assessable	2	Not assessable	1		

*e.g. unlikely to definite or probable to definite. ^e.g. definite to probable or probable to possible.


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Patient SPEARs

Fifteen (15) patient SEAR events were reported. Six (6) reports were after HPC Marrow transplant, 7 after HPC Apheresis transplant and 2 after HPC-Cord transplant.

The following type of incidents were reported:

Pulmonary	3
Infection	3
Transmitted bacterial infection	2
Cytogenetic abnormality	2
Cardiovascular	1
Allergy	1
Malignancy	1
Transfusion reaction	1
Dysplastic donor cells	1


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Assessment of imputability

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Reported imputability	N	Assessed imputability	N	Imputability changed	N
Definite	4	Definite	6	Agreed	10
Probable	3	Probable	1	Upgraded*	3
Possible	2	Possible	2	Downgraded^	0
Unlikely	3	Unlikely	1	To excluded	2
Excluded	1	Excluded	3	To not assessable	0
Not assessable	2	Not assessable	2		

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Product SPEARs

Thirty (30) product-related incidents were reported. After evaluation 1 report was considered a non-report. Five (5) reports were concerning a HPC Marrow product, 12 concerning a HPC Apheresis product, 1 concerning a MNC Apheresis product, 9 concerning a HPC-Cord product and in 3 reports the product type was unknown.

The following type of incidents were reported:

Low cell count	8
Low cell viability	3
Leaking bag	3
Clotted product	3
Delayed infusion of the graft	2
Product arrived thawed	2
CT stage donor sample mix-up	1
Discrepancy at collection report	1
High RBC count in product	1
High WBC count in product	1
Final clearance donor sample mix-up	1
Infection in donor, no product	1
Poor product collection, no infusion	1
Pre collection label error	1
Product not used/transplant cancellation	1


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Assessment of imputability

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Reported imputability	N	Assessed imputability	N	Imputability changed	N
Definite	5	Definite	4	Agreed	17
Probable	0	Probable	0	Upgraded*	4
Possible	3	Possible	2	Downgraded^	0
Unlikely	2	Unlikely	1	To excluded	5
Excluded	1	Excluded	6	To not assessable	4
Not assessable	19	Not assessable	17		

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Transport Issues

Six (6) transport-related events were reported. Three (3) reports were concerning transport of an HPC Apheresis product and 3 concerning transport of an HPC-Cord product.

The following type of incidents were reported:

Product arrived thawed	2
Courier was denied boarding	1
Exploded bag	1
Low cell count at collection delaying transport	1
Delayed collection caused longer waiting time for the courier and a problem with refreezing the transport cooler	1

Assessment of imputability

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

Reported imputability	N	Assessed imputability	N	Imputability changed	N
Definite	0	Definite	0	Agreed	2
Probable	1	Probable	1	Upgraded*	2
Possible	1	Possible	0	Downgraded^	0
Unlikely	0	Unlikely	1	To excluded	1
Excluded	0	Excluded	1	To not assessable	1
Not assessable	4	Not assessable	3		

*e.g. unlikely to definite or probable to definite. ^e.g. definite to probable or probable to possible.