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S(P)EAR COMMITTEE ANNUAL REPORT 2018

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, Ann Woolfrey, Rachel Pawson, Monique Jöris

The committee received and considered 206 S(P)EAR incidents during 2018, compared to 367 in 2017. They were received from 18 organisations in 14 countries.

1 Overview

	Harm to donor	Harm to recipient	Risk of harm	Total
Total reported	152	18	36	206
- Considered not a S(P)EAR	1	3	20	24
Timeframe (total)	151	15	16	182
- Donor assessment	-	-	2	2
- Mobilisation	18 (13 collection completed, 5 cancelled)	-	1	19
- Collection	12 (9 collection completed, 3 stopped)	2	7	21
- Distribution	-	1	1	2
- Processing	-	1	2	3
- Transport	-	1	2	3
- Transplant	-	10	1	11
- Short term (<30 days)	27	-	-	27
- Long term (>=30 days)	94	-	-	94
Graft type (total)	151	15	16	182
- Pre-collection samples	-	-	1	1
- HPC-Marrow	26	4	4	34
- HPC-Apheresis	123	7	7	137
- HPC-Cord	-	4	3	7
- DLI	2	-	1	3

2 Harm to donor

One-hundred-fifty-one (152) harm to donor incidents were considered. After evaluation 1 incident was considered as 'not a SEAR', these will be discussed under a separate header.

Twenty-six (26) incidents occurred after HPC-Marrow harvest, 123 after HPC-Apheresis collections and 2 after DLI collection. Ninety-three (93) affected donors are male, 56 are female and 2 have no sex recorded.

2.1 The following type of incidents were reported

2.1.1 Malignancy

Fifty-seven (57) malignancies occurred in the donor, all occurred in 30 days or more after donation.

Type	n	Time after donation in years [median (range)]
Breast cancer	17	4 (1 – 8)
Haematological malignancies*	10	4 (1 – 7)
Renal cancer	6	4 (3 – 6)
Testicular cancer	6	2 (1 – 4)
Colorectal cancer	4	3 (1 – 6)
Ovarian cancer	3	1 (1 – 1)
Melanoma	2	4 (3 – 5)
Bone cancer	2	7 (6 – 7)
Other^	7	6 (1 – 7)
Total	57	4 (1 – 8)

*Haematological malignancies include: 2 B-cell lymphoma, 2 Hodgkin lymphoma, 2 NHL, 1 leukemia, 1 Waldenström's macroglobulinemia, 1 T cell lymphoma and 1 CLL. ^Other malignancies include: 1 lung cancer, 1 tongue cancer, 1 bladder cancer, 1 thyroid cancer, 1 intracranial neoplasm, 1 bile duct neoplasm and 1 Anaplastic Oligodendroglioma.

2.1.2 Autoimmune disorders

Twenty-eight (28) autoimmune disorders occurred in the donor in 30 days or more after donation and 3 occurred within 30 days after donation.

Type	n	Time after donation in years [median (range)]
Multiple Sclerosis	12	4 (1 month – 6)
Rheumatoid Arthritis	4	4 (2 – 7)
Crohn's disease	3	1 (1 – 3)
Ankylosing spondylitis	3	4 (2 – 4)
Sarcoidosis	2	2 (1 – 2)
Other*	7	1 (2 weeks – 2)
Total	31	2 (2 weeks – 7)

*Other immune disorders include: 1 colitis ulcerosa, 1 eosinophilic esophagitis, 1 pemphigus vulgaris, 1 psoriasis, 1 psoriatic arthritis, 1 transverse myelitis and 1 vitiligo.

2.1.3 Other incidents

Forty-two (42) other incidents occurred in the donor in 30 days or more after donation, 46 occurred within 30 days after donation, 22 during mobilisation, 17 during collection and 1 UNK.

Type	n	Mobilisation (n)	Collection (n)	Short term in days [n (range)]	Long term in months [n (range)]
Allergic reaction	12	6	1	5 (1 - 30)	-
Local trauma	10	-	5	5 (1 - 30)	-
Infection	7	-	-	7 (1 – 21)	-
Cardiovascular	4	3	-	-	1 (1)
Splenic rupture	2	1	-	-	1 (6)
Cerebrovascular	1	-	-	1 (15)	-
Other*	27	8	6	6 (1 - 30)	7 (1 – 5)
Total	63	18	12	24 (1 – 30)	9 (1 – 6)

*Other incidents include: 3 CNS, 3 thrombosis/embolic, 2 citrate toxicity, 2 syncope, 1 social/psychological, 1 chest pain, 1 asthma attack, 1 adverse reaction to Filgrastim Teva, 1 gastrointestinal, 1 hypocalcemia, 1 lypothymia, 1 macrohematuria, 1 compartment syndrome in the leg, 1 synovitis, 1 keratitis marginalis, 1 perianal haemorrhage, 1 renal damage, 1 tinnitus, 1 xanthogranuloma juvenile, 1 keratoconjunctivitis sicca and 1 dizzyness/nausea.

2.2 Assessment of imputability

The committee assessed each incident 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	26	Agreed	124
Probable	17	Probable	17	Upgraded*	18
Possible	18	Possible	12	Downgraded^	3
Unlikely	76	Unlikely	79	To excluded	3
Excluded	15	Excluded	16	To not assessable	1
Not assessable	3	Not assessable	1	Not a SEAR	1
UNK	2	Not a SEAR	1	Cannot be determined (imputability reported UNK)	2

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

2.3 Incidents considered not a SEAR

Type	n	Why?	Report in the future?
The donor was diagnosed with MGUS (IgG lambda) 13 years after donation	1	Only a pre-malignancy AND >10yrs after donation	NO (YES if in close temporal connection)

3 Harm to recipient

Fifteen (15) harm to recipient incidents were reported. After evaluation 3 incidents were considered as 'not a SPEAR', these will be discussed under a separate header.

Four (4) incidents followed after HPC-Marrow transplant, 7 after HPC-Apheresis transplant and 4 after HPC-Cord transplant. Two (2) harm to recipient incidents occurred during collection, 1 during distribution, 1 during processing, 10 during transplant and 1 during transport.

3.1 The following type of incidents were reported

Pulmonary	3
Potential product quality issue	2
Engraftment failure	2
Product quality issue	2
Transmitted bacterial infection	2
Infusion related non-specific symptoms	1
Allergic reaction	1
Cardiovascular	1
Other, suspected infection	1

3.2 Assessment of imputability

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

Reported imputability	n	Assessed imputability	n	Imputability changed	n
Definite	10	Definite	7	Agreed	11
Probable	3	Probable	4	Upgraded*	0
Possible	1	Possible	1	Downgraded^	1
Unlikely	0	Unlikely	0	To excluded	0
Excluded	1	Excluded	1	To not assessable	1
Not assessable	1	Not assessable	1	Not a SPEAR	3
UNK	2	Not a SPEAR	3	Cannot be determined (imputability reported UNK)	2
		Not applicable	1		

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

3.3 Incidents considered not a SPEAR

Type	n	Why?	Report in the future?
Product with low cellularity	2	Still > 0.5 X10^6 /kg	No, as long as engrafted AND no “error” occured
Positive result in Ac Anti-HCV. PCR and confirmation tests were negative.	1	False positive screening tests are EXPECTED in ~1%	No

4. Risk of harm

Thirty-six (36) risk of harm incidents were reported. After evaluation 20 incidents were considered as 'not a SPEAR', these will be discussed under a separate header.

Four (4) incidents were concerning a HPC-Marrow donation, 7 concerning a HPC-Apheresis donation, 3 concerning a HPC-Cord product, 1 concerning a pre-collection sample and 1 concerning a DLI. Seven (7) risk of harm incidents occurred during collection, 2 at donor assessment, 1 during mobilisation, 1 at distribution, 2 during processing, 2 during transport and 1 during transplant.

4.1 The following type of incidents were reported

Product quality issue	8
Delayed arrival of product	3
No product collected	1
Potential quality issue	1
Other	3

4.2 Assessment of imputability

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

Reported imputability	n	Assessed imputability	n	Imputability changed	n
Definite	4	Definite	5	Agreed	3
Probable	3	Probable	0	Upgraded*	3
Possible	1	Possible	0	Downgraded^	0
Unlikely	1	Unlikely	1	To excluded	2
Excluded	7	Excluded	3	To not assessable	3
Not assessable	2	Not assessable	4	Not a SPEAR	20
UNK	18	Not a SPEAR	20	Cannot be determined (imputability reported UNK)	5
		Not applicable	3		

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

4.3 Incidents considered not a SEAR

Type	n	Why?	Report in the future?
Product quality issue	7	No consequences for recipient	YES; if educational / "error"; NO if expected (e g , BM contamination with skin bacteria; low but still adequate cell dose)
Potential product quality issue	3	No consequences for recipient	YES; if educational / "error"; NO if expected (e g , BM contamination with skin bacteria; low but still adequate cell dose)
Delayed arrival of the product	2	No consequences for recipient	YES; if educational / "error"; NO if expected (e g , BM contamination with skin bacteria; low but still adequate cell dose). No, if unavoidable, well handled and no consequences for the (international) system as a whole.
Cytogenetic abnormalities in donor cells	1	No consequences for recipient	Only if DISEASE transmitted
No product collected	1	Donor not *consenting* to a CVC is not a SAE	n/a; depends on the reason why peripheral access was not possible
Other	6	n/a (mostly deemed neither severe nor educational)	YES; if educational / "error"; NO if expected (e g , BM contamination with skin bacteria; low but still adequate cell dose)

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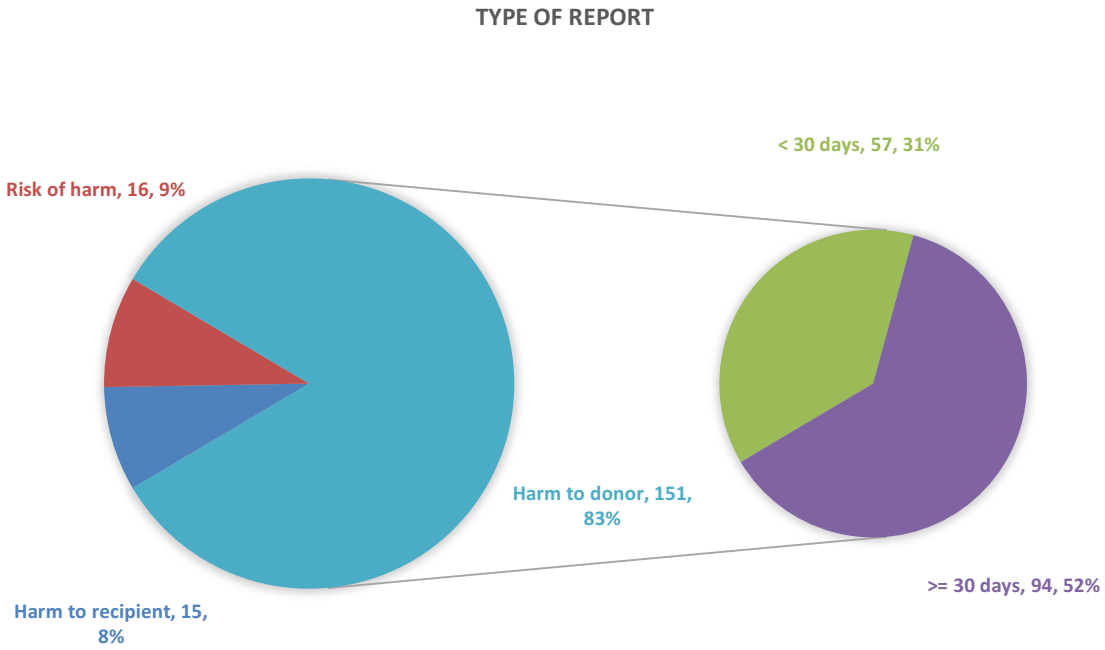
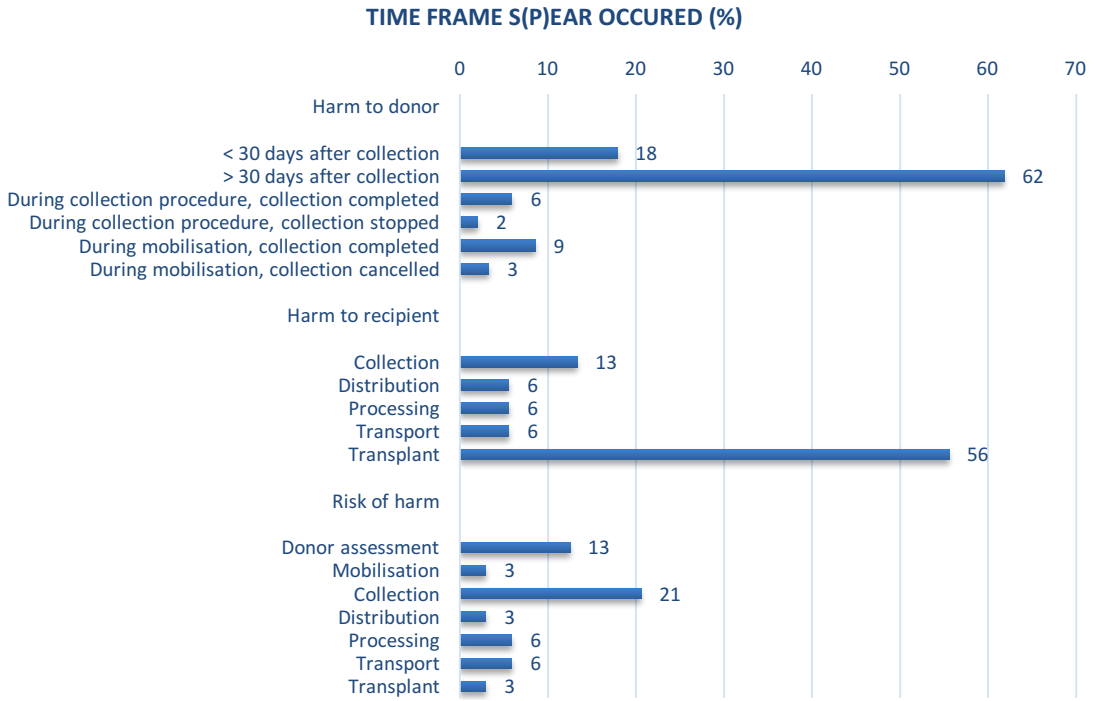
5 Graphs





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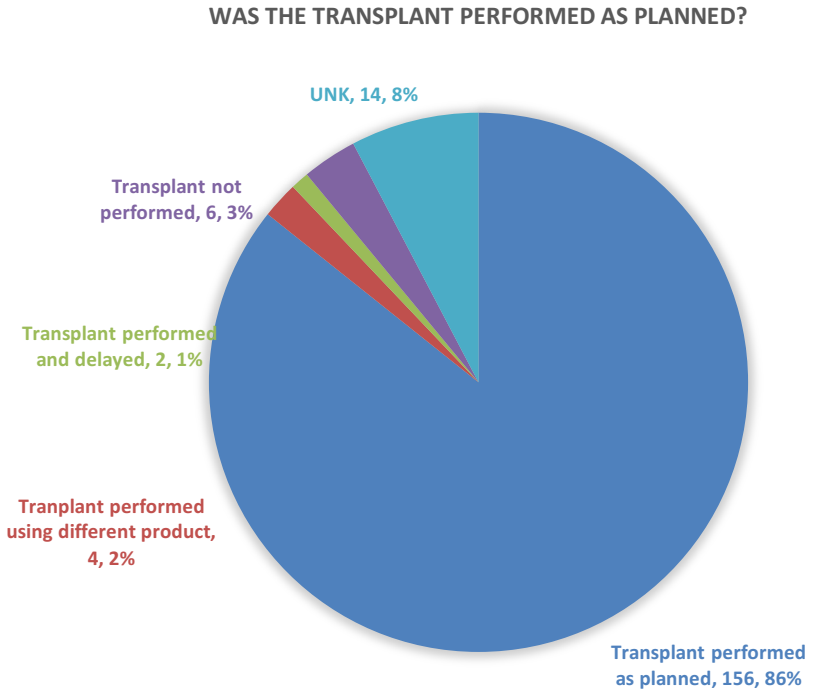

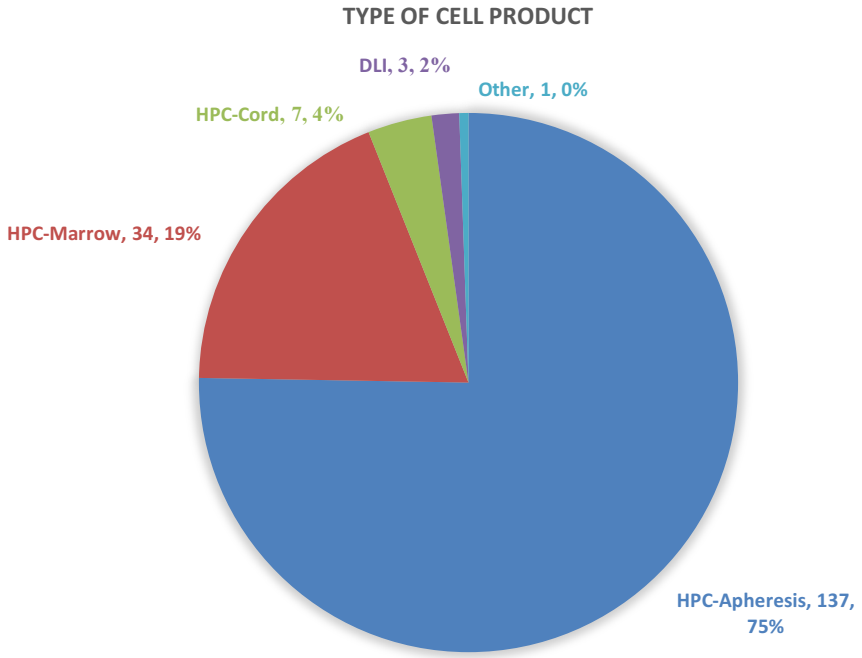

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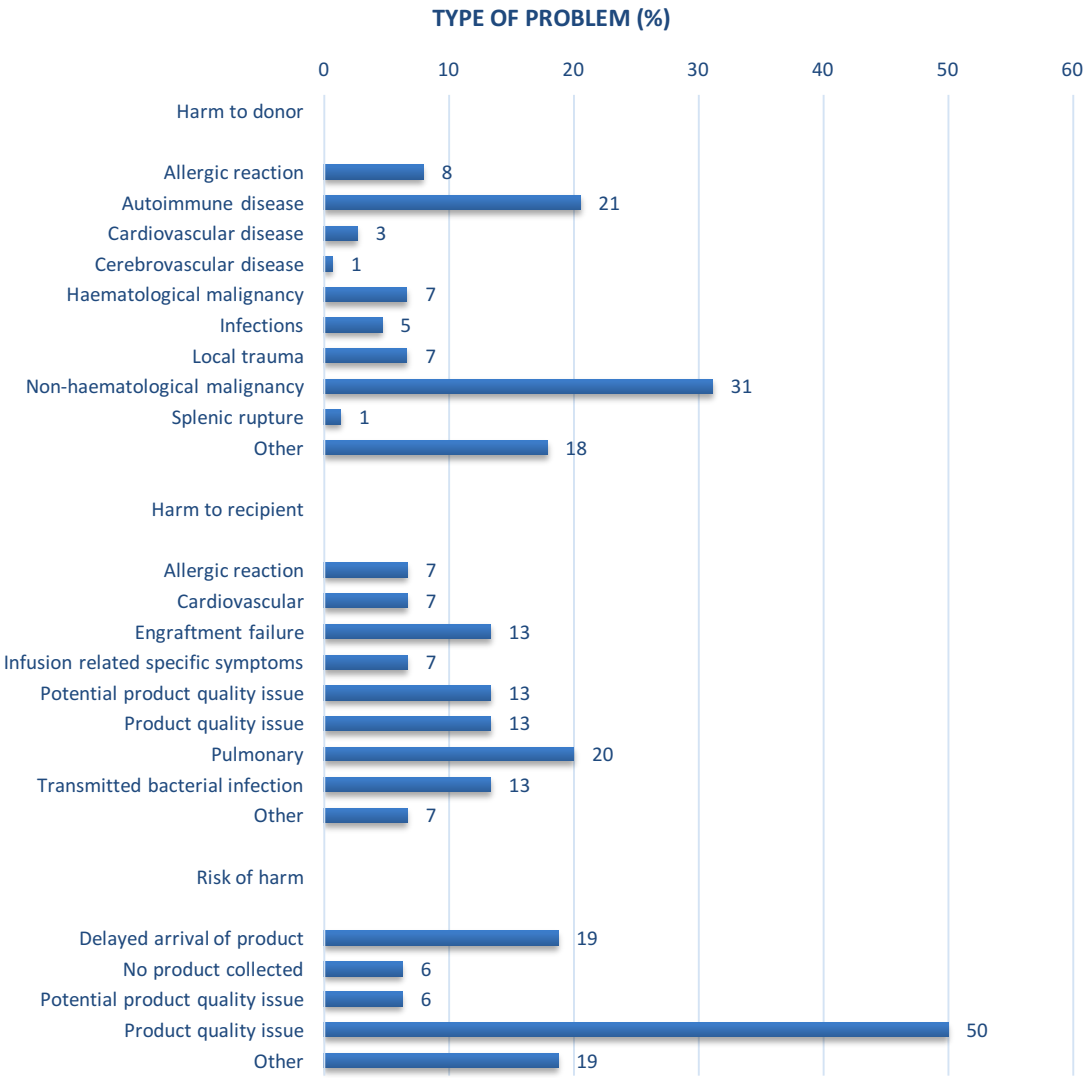

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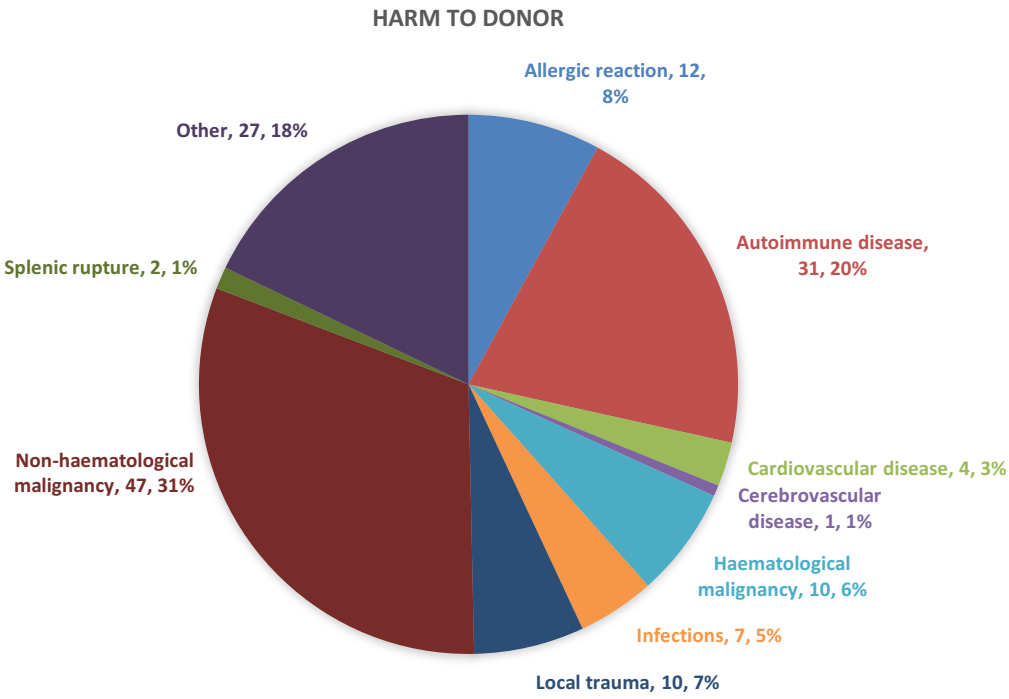

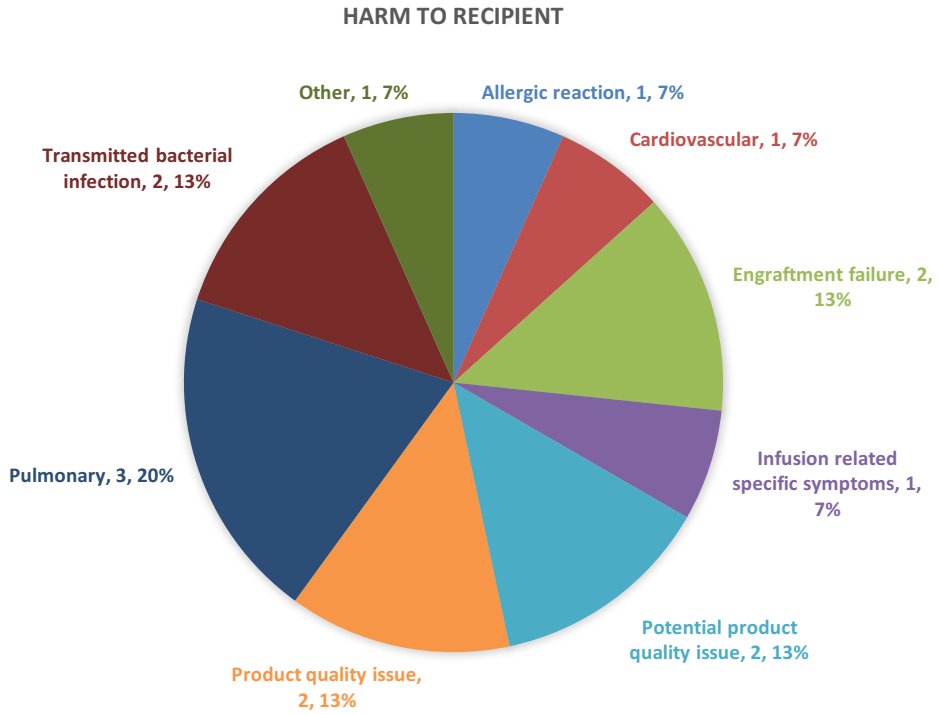

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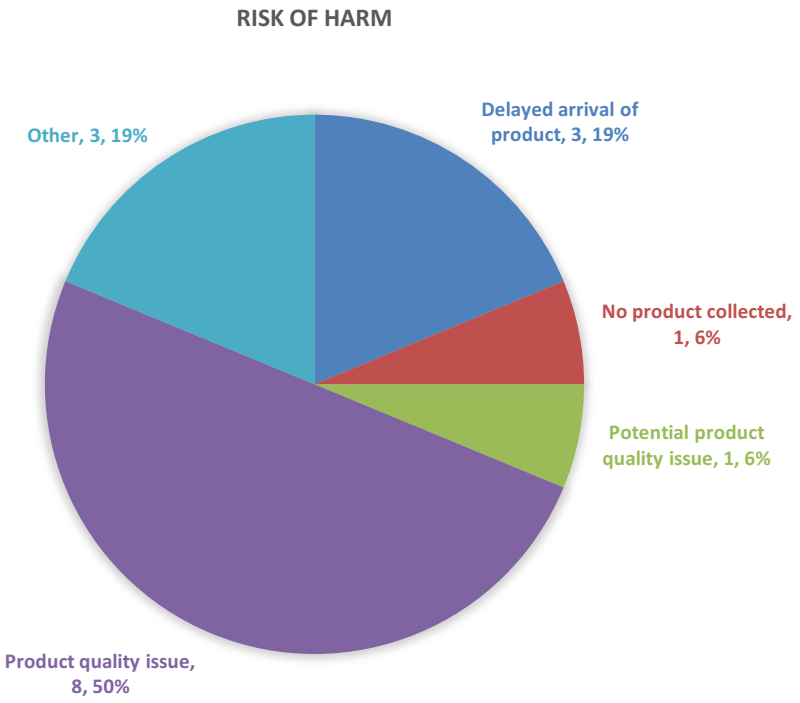

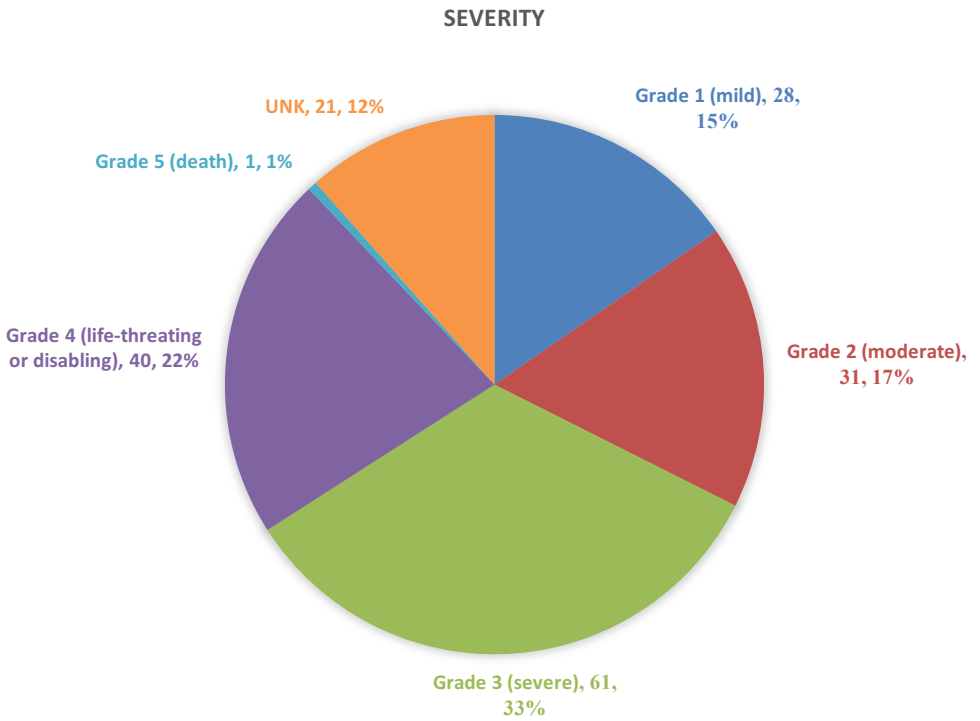

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