

	S(P)EAR Committee Annual Report - year 2011			
	Document Type:	Annual Report	WG/Committee:	SEAR
	Document Reference:	20120821-SEAR-Annual Report 2011	Other (specify):	
	Version:	2	Approved by:	SEAR
	Drafting Date:		Approval date:	20120821
	Status	Public		

**S(P)EAR review committee:** Bronwen Shaw - Chair (UK), Jeff Szer – vice-chair (Australia), Jeremy Chapman (Australia), Mirjam Fechter (Netherlands), William Hwang (Singapore), Matti Korhonen (Finland), Willis Navarro (USA), Lydia Foeken (NL- non-voting), Brian Lindberg (USA - non-voting)

In 2011, 203 S(P)EARs were reported, the majority of these were reported using paper forms.

Each SEAR and SPEAR was reviewed by the S(P)EAR committee and imputability was assigned, in some cases more information was first sought from the reporting registry. In some cases a final assignment could not be made.


It was recognised that there is added value to the membership through presenting the imputability assignments and we have presented the data in that manner. S(P)EAR highlighted in red show a difference in imputability assignment between the registry and the committee.

It should be remembered that for SPEAR the imputability relates to harm to the patient, not primarily to the quality or other aspects of the product (thus even if there is a definite quality issue with a product, the imputability may be 'excluded' if no harm came to the patient).


Not assessable is often assigned in SPEAR if engraftment data is unknown

In future years (since the move to an online reporting system), the timing (early or late) of the S(P)EAR will also be reported.

Year of donation	Stem cell source	SEAR	Imputability assignment	
			Registry	S(P)EAR committee
2001	BM	Stomach cancer 8 years post donation	Excluded	Excluded
2002	BM	Pain at collection site 17 months post donation. MRI showed prolapsed disc which may have occurred shortly after donation	Possible	Possible
2002	BM	Haematoma at BM site required surgical removal	Definite	Definite
2003	BM	Wrist pain with probably tendon injury from canulation. Physiotherapy required, recovered	Probable	Definite
2003	BM	Breast cancer 2 years post donation	Definitely not	Excluded
2003	BM	Prolonged pain after marrow donation. MRI showed BM oedema (persistent on repeat MRI 3 months later - which also showed disc prolapse)	Definite (persistent pain)	Definite
2003	BM	Thrombosis r forearm due to IV access. 30 day recovery	Definite	Definite
2004	BM	Primary kidney adenocarcinoma 4 years after donation	Definitely not	Excluded
2004	BM	Osteomyelitis. 4 weeks of in hospital iv antibiotics required	Definite	Definite
2010	BM	Pain in the iliac crest for 3 months requiring physiotherapy. 1 extra day hospitalisation.	Definitely	Definite
2010	BM	Chronic pain syndrome with damage to the right radial nerve caused by extensive haematoma from venepuncture during marrow collection. Analgesia, steroids and physiotherapy required.	Definitely	Definite

	S(P)EAR Committee Annual Report - year 2011			
	Document Type:	Annual Report	WG/Committee:	SEAR
	Document Reference:	20120821-SEAR-Annual Report 2011	Other (specify):	
	Version:	2	Approved by:	SEAR
	Drafting Date:		Approval date:	20120821
	Status	Public		


2010	BM	Schwannoma 16 months post donation.	Unlikely	Excluded
2011	BM	Low oxygen levels and respiratory symptoms in recovery room. Donor on antibiotics prior to donations. Hospitalised for 1 day.	Possible	Probable
2011	BM	Donor collapsed 10 hours post BM harvest. Unresponsive and no pulse felt. CPR instituted and continued for 3 minutes. Cardiac output not lost. Hb 10.6 prior to harvest and 6 post - 2 unit allogeneic blood transfusion. 2 extra days in hospital. 30 days to full recovery.	Definite	Definite
2011	BM	Laryngospasm post extubation. Needed to be re-intubated. 2 day admission. Resolved completely.	Definitely	Definite
2011	BM	Dysphagia after extubation, uvula elongation. Treated with steroids. 7 day recovery.	Definite	Definite
2011	BM	Donor unwell and dropped their BP 16 hours post harvest in hospital. Needed fluid resuscitation and 1 unit of allogeneic blood (had also received 1 autologous unit)	Not assessable	Definite
2011	DLI	Anaphylactic response to apheresis set with bronchospasm and rhinitis. Collection successful. PBSC collection 5 months previously.	Definitely	Definite
2000	PBSC	Invasive ductal carcinoma of the breast 2002	Probably not	Unlikely
2000	PBSC	Phaeochromocytoma 5 years post donation	Probably not	Unlikely
2001	PBSC	Oesophageal cancer 2007	Probably not	Unlikely
2001	PBSC	Seminoma 3.5 years post donation	Probably not	Unlikely
2002	PBSC	T-ALL. Diagnosed in 2009. Donor has died.	Probably not	Unlikely
2002	PBSC	Hyperthyroid crisis with secondary cardiac failure at home 14 days post second apheresis. Autoimmune thyroiditis with polyneuropathy. No PMH. Second donation (first also PBSC 17 months prior)	Probably	Probable
2002	PBSC	Joint swelling and elevated LFT 12 months post donation. Donor B*27 +.	Probably not	Unlikely
2002	PBSC	Donor had complete alopecia 18 months after 2nd donation. Had history of alopecia areata, but this was not known at medical	Possibly	Possibly
2003	PBSC	CML 8 years after donation (2 PBSC donations 4 months apart)	Probably not	Unlikely
2003	PBSC	Donor had a stroke 12 months after second donation. PMH of hypercholesterolaemia and smoking.	Definitely not	Unlikely
2004	PBSC	Malignant melanoma 4 years post donation	Not assigned	Unlikely
2004	PBSC	Colon carcinoma 7 months post DLI	Definitely not	Unlikely
2004	PBSC	Transverse myelitis 3 years post donation	Not assigned	Possible
2005	PBSC	Follicular thyroid cancer 2008	Probably not	Unlikely
2005	PBSC	Donor was unable to proceed with donation due to severe breathlessness during GCSF. No medical intervention except stopping GCSF needed. Psychological factors thought to play a role.	Probably	Definite
2005	PBSC	Donor suffered from ITP 3 weeks after collection. Unknown what treatment given but now recovered.	Possible	Possible
2005	PBSC	Hypertonus 2 months after donation, 8 months later thrombosis left eye with retinal detachment	Probably not	Unlikely
2005	PBSC	Breast cancer 1 year post	Probably not	Unlikely
2006	PBSC	Breast cancer	Probably not	Unlikely
2006	PBSC	Hashimoto's disease (TSH 204) and vitiligo within	Possibly	Possible

	S(P)EAR Committee Annual Report - year 2011			
	Document Type:	Annual Report	WG/Committee:	SEAR
	Document Reference:	20120821-SEAR-Annual Report 2011	Other (specify):	
	Version:	2	Approved by:	SEAR
	Drafting Date:		Approval date:	20120821
	Status	Public		

		6 months of donation. History of latent hypothyroidism (TSH 6.36)		
2006	PBSC	Seminoma 1 year post donation	Probably not	Unlikely
2006	PBSC	Paroxysmal AF 13 days post collection, required cardioversion	Probably not	Unlikely
2006	PBSC	Donor diagnosed with hypothyroidism 5 years post donation. TC informed. Patient was diagnosed 1 year post transplant with hypothyroidism. Both patient and donor controlled on replacement therapy	Unlikely	Possible
2006	PBSC	Fatal PE 4 years post donation	Excluded	Excluded
2007	PBSC	Metastatic colon cancer 2009	Probably not	Unlikely
2007	PBSC	Colorectal carcinoma 40/12 post donation	Probably not	Unlikely
2007	PBSC	ITP requiring steroids 3 years after donation	Probably not	Unlikely
2007	PBSC	MS 3 years post second PBSC collection	Probably not	Unlikely
2007	PBSC	AML diagnosed 2011 - death due to AML (3 days post diagnosis)	Probably not	Unlikely
2007	PBSC	Neutropaenia 1 year post donation. No clinical effects. BM biopsy performed.	Possible	Possible
2007	PBSC	Rheumatoid arthritis several years post donation	Probably not	Unlikely
2007	PBSC	Lung carcinoma 07/2011	Definitely not	Unlikely
2007	PBSC	Bilateral ovarian carcinoma 44 months post donation	Unlikely	Unlikely
2008	PBSC	Atypical athropathia psoriatica requiring methotrexate, but long history of psoriasis vulgaris (12 months post)	Probably not	Unlikely
2008	PBSC	MI (1 year post donation). Dilated cardiomyopathy	Probably not	Unlikely
2008	PBSC	Crohns disease 17 months post PBSC (had donated BM ~3 years prior)	Probably not	Unlikely
2009	PBSC	Hodgkin lymphoma	Probably not	Unlikely
2009	PBSC	Erythema of legs after 3rd GCSF injection. Inpatient treatment, topical steroids. Cells collected	Probable	Probable
2009	PBSC	Allergic urticaria and itching hives during GCSF injections. Continued for 6 months - requiring steroids post collection. History of allergic reaction to eye drops.	Definite	Probable
2009	PBSC	Cerebral infarction, basilar artery haemorrhage. 3 months post collection	Probably not	Unlikely
2009	PBSC	Crohn's disease 2 years post collection	Probably not	Unlikely
2009	PBSC	Acute sarcoidosis diagnosed 14 days post collection. Resolved after 3 months.	Possibly	Possible
2009	PBSC	Oesophageal cancer 2 years post donation	Probably not	Unlikely
2009	PBSC	Gastric malt lymphoma 11 months post PBSC (second donation - first PBSC 38 days prior). Required only helicobacter eradication	Probably not	Unlikely
2009	PBSC	Auto-immune hypothyroidism 2 months post donation	Possible	Possible
2009	PBSC	MGUS diagnosed 2011 (at request for DLI)	Probably not	Unlikely
2009	PBSC	Auto-immune inflammatory polyarthritis 1 year post donation	Unlikely	Unlikely
2009	PBSC	Thyroid cancer 2 years post donation	Unlikely	Unlikely
2010	PBSC	Elevated liver enzymes during GCSF. Normalised 30 days after donation.	Probable	Probable
2010	PBSC	Left sided palsy and convulsions 1 month post donation. Brain surgery - histopathology inconclusive, haemorrhage of unknown origin.	Possible	Possible

Document Type:	Annual Report	WG/Committee:	SEAR
Document Reference:	20120821-SEAR-Annual Report 2011	Other (specify):	
Version:	2	Approved by:	SEAR
Drafting Date:		Approval date:	20120821
Status	Public		

2010	PBSC	Severe headache requiring imigran and hospital admission at home (3 days after apheresis). CT head normal. Donation as planned.	Possible	Possible
2010	PBSC	Acute pyogenic necrotising and haemorrhagic enteritis requiring surgery. Occurred 3 days post apheresis. treating physician thought a link to filgastrim possible.	Possible	Possible
2010	PBSC	Ovarian cancer. Reported 7 months after donation	Definitely not	Unlikely
2010	PBSC	Pulpitis sicca (atopic dermatitis) both hands 20 days post collection - no previous history	Possibly	Possible
2010	PBSC	Ankylosing spondylitis diagnosed 10 months post donation. (B27 neg). Back pain and arthralgia prior to donation.	Probably not	Unlikely
2010	PBSC	Wegener's granulomatous. 3 months post donation	Probably not	Possible
2010	PBSC	Multiple liver haemangiomas and elevated LFT 6 months post donation. At work up there were no liver abnormalities (normal ultrasound)	Probably not	Possible
2010	PBSC	De quervains thyroiditis 3 months post PBSC - having treatment	Probably not	Unlikely
2010	PBSC	Left retinal detachment 5 months post PBSC	Probably not	Unlikely
2010	PBSC	Ulcerative colitis 5 weeks after PBSC, acute gastroenteritis 1 week prior to donation on holiday.	Possibly	Possible
2010	PBSC	Classical Hodgkin disease stage 1A 6 months post PBSC	Probably not	Unlikely
2010	PBSC	Fibromyalgia 6 months post donation	Probably not	Unlikely
2010	PBSC	Diffuse alopecia 2-3 months post donation	Possible	Possible
2010	PBSC	Ulcerative colitis 4 months post donation	Possible	Possible
2010	PBSC	Disabling hip pain	Possible	Possible
2010	PBSC	Balanced reciprocal translocation (discovered in patient post transplant). Increased miscarriage rate - donor needed genetic counselling	Definitely not	Unlikely
2010	PBSC	Breast cancer 11 months post donation	Unlikely	Unlikely
2011	PBSC	Hypertension and tiredness after donation (PMH hypertension)	Possible	Possible
2011	PBSC	After first dose of GCSF donor collapsed. Recovered without intervention. Mobilisation and harvest continued.	Probable	Probable
2011	PBSC	Otitis media, pneumonia and renal insufficiency 2 days after donation. 16 days inpatient. Not fully returned to work.	Possible	Possible
2011	PBSC	Macroscopic haematuria on the fourth day of mobilization. Donor had ultrasound and CT examination on the day of collection – 13 mm benign cyst found in cortical area of the kidney. Donor was checked by nephrologist and urologist. Preliminary finding: aseptic cystitis.	Probably	Not assessable
2011	PBSC	Thrombophlebitis right forearm from peripheral line. Required short term heparin	Definitely	Definite
2011	PBSC	Herpes zoster diagnosed during second apheresis procedure. 14 days of aciclovir	Possibly	Possible
2011	PBSC	Trigeminal neuralgia 21 days post DLI (unstimulated) collection	Possibly	Unlikely
2011	PBSC	Unable to collect via peripheral veins. Unable to insert CVC in right Femoral vein. Femoral artery punctured - pain and ?aneurysm. Compression for	Definitely	Definite

	S(P)EAR Committee Annual Report - year 2011			
	Document Type:	Annual Report	WG/Committee:	SEAR
	Document Reference:	20120821-SEAR-Annual Report 2011	Other (specify):	
	Version:	2	Approved by:	SEAR
	Drafting Date:		Approval date:	20120821
	Status	Public		

		24 hours required. 2 days hospitalisation. Resolved.		
2011	PBSC	Acute gouty arthritis of left ankle on D3 of GCSF. Analgesia required resolved in 4 days. PMH hypertension and obesity (BMI 36)	Definitely	Probable
2011	PBSC	3 hours after 2nd GCSF injection donor experienced mild dysphagia. Same dysphagia recurred 5 days after collection due to 'stress'.	Probably	Probable
2011	PBSC	Nerve damage from peripheral line with pain and paraesthesia back of the hand	Definitely	Definite
2011	PBSC	Admitted 48 hours after 2nd collection with fever, abdominal pain and distention, constipation, bone pain. Symptomatic treatment and 7 day inpatient admission. Fully resolved	Possible	Probable
2011	PBSC	Near syncope after discharge home. 1litre iv fluid given (at home) full recovery	Probable	Probable
2011	PBSC	25cm haematoma on donor arm 5 days post apheresis. Painful but not swollen, resolved spontaneously after 1 week	Definite	Definite
2011	PBSC	Tachycardia during PBSC injections (160-180). Resolved with beta-blockers. History of palpitations	Probable	Probable
2011	PBSC	During a pause in the first apheresis the donor went to the toilet, collapsed and was noted to have 'spasms' ?vaso-vagal associated convulsion. Full recovery.	Definite	Definite
2011	PBSC	Incomplete lesion of radialis nerve from venepuncture. 200 days to recovery	Definite	Definite
2011	PBSC	Urticaria and allergic asthma 5 months post donation	Possible	Unlikely
2011	PBSC	Herpes zoster at home after apheresis completed. Iv aciclovir 6 days	Possible	Possible
2011	PBSC	Acute tonsillar bleeding day 2 of GCSF. No treatment. Recovered. Collection went ahead	Possible	Possible
2011	PBSC	Painful calf spasm D3 of GCSF. Admitted and thrombosis excluded. Resolved with pain killers.	Definite	Probable
2011	PBSC	Acute heart insufficiency/ failure (ejection fraction 15 %) due to viral myocarditis, secondary to parvovirus B19 (positive in blood sample). 12 days post donation.	Possible	Unlikely
unknown	PBSC	Melanoma 5 months post	Probably not	Unlikely
2011	PBSC	Intracranial haematoma 10 days post apheresis	Possible	Possible
2009	PBSC	MS 1 year after donation	Probably not	Unlikely
2010	PBSC	Thrombophlebitis from both peripheral lines	Definitely	Definite
2008	PBSC	MS 11 months after donation	Probably not	Unlikely
2011	PBSC	Donor death from complications of CVC insertion		Definite
1996	BM	Ovarian carcinoma	Definitely not	Unlikely
1997	BM	CLL	Definitely not	Unlikely
2006	BM	Melanoma	Definitely not	Unlikely
2010	BM	Cardiac arrhythmia 6 weeks post donation. Not present at pre-donation medical	Possibly	Unlikely /possible
2010	BM	Osteomyelitis sacrum, still recovering (pain)	Definitely	Definite

Document Type:	Annual Report	WG/Committee:	SEAR
Document Reference:	20120821-SEAR-Annual Report 2011	Other (specify):	
Version:	2	Approved by:	SEAR
Drafting Date:		Approval date:	20120821
Status	Public		

Year	BM	Condition	Assessment	Outcome
2010	BM	<b>Prolonged orthostatic dysregulation</b>	<b>Definitely</b>	<b>Possible</b>
2010	BM	Thrombophlebitis from the peripheral venous line. Aggravated by subsequent GCSF mobilised pbscx2 within next 4 months	Definitely	Definite
2010	BM	Symptomatic anaemia following harvest requiring allogeneic blood	Definitely	Definite
2006	PBSC	Multiple sclerosis	Probably not	Unlikely
2006	PBSC	Renal cell carcinoma	Probably not	Unlikely
2007	PBSC	<b>Rheumatoid arthritis</b>	<b>Probably not</b>	<b>Unlikely /possible</b>
2008	PBSC	Breast cancer	Probably not	Unlikely
2009	PBSC	Giant cell tumour left radius	Probably not	Unlikely
2009	PBSC	Breast cancer 2010	Probably not	Unlikely
2009	PBSC	Testicular cancer 2010	Probably not	Unlikely
2009	PBSC	ALL (father died from 'leukaemia')	Probably not	Unlikely
2009	PBSC	Thrombophlebitis from the apheresis line. Antibiotics required. 50 day recovery	Definitely	Definite
2009	PBSC	<b>Chronic keratitis &gt; 6 months. Topical therapy</b>	<b>Probably not</b>	<b>Possible</b>
2009	PBSC	Ulcerative colitis developed 2 months post donation	Possibly	Possible
2009	PBSC	<b>Rheumatoid arthritis 6/12 post donation (positive family history)</b>	<b>Probably not</b>	<b>Possible</b>
2010	PBSC	<b>Abnormal liver function tests. Abdominal pain. No cause found. Ultrasound normal</b>	<b>Probably not</b>	<b>Possible</b>
2010	PBSC	Chest tightness during collection. All tests normal. Completely resolved. Collection stopped early but requested cell number collected.	Probably	Probable
2010	PBSC	Hospital admission due to severe pre donation pain. Recovered in 2 days	Definitely	Definite
2010	PBSC	PBSC terminated after 3 attempts due to severe citrate toxicity/hypocalcaemia. Donor donated BM	Definitely	Definite
2010	PBSC	Tetany on machine. Resolved, collection complete	Definitely	Definite
2010	PBSC	Breast cancer	Probably not	Unlikely
2010	PBSC	Breast cancer	Probably not	Unlikely
2010	PBSC	Abdominal pain during 2nd apheresis - normal ultrasound. 5 hours later at home had more pain, admitted, probable cholecystitis. 3 day admission	Possibly	Possible
2010	PBSC	D2 of GCSF intractable vomiting. Hospitalised. Collection went ahead	Definitely	Definite
2010	PBSC	<b>MI 4 weeks after donation (obese BMI30, high BP, smoker)</b>	<b>Probably not</b>	<b>Unlikely /possible</b>
2010	PBSC	Pilonidal sinus 6 weeks post donation. Surgery	Probably not	Unlikely
2010	PBSC	Uveitis anterior R eye (3 days after collection)	Possibly	Possible
2010	PBSC	Epididymitis L testis, urethritis. During GCSF injections. Antibiotics, resolved	Probably not	Unlikely
2010	PBSC	Testicular cancer	Definitely not	Unlikely
2010	PBSC	Breast cancer 8 months post	Probably not	Unlikely
2011	PBSC	Unable to obtain successful peripheral access for apheresis. Donor refused central access on day 2. No collection possible	Definitely	Definite

Document Type:	Annual Report	WG/Committee:	SEAR
Document Reference:	20120821-SEAR-Annual Report 2011	Other (specify):	
Version:	2	Approved by:	SEAR
Drafting Date:		Approval date:	20120821
Status	Public		

Year of donation	Stem cell source	SPEAR	Imputability assignment	
			Registry	S(P)EAR committee
2011	BM	Donor centre expressed reservations about clearing the donor due to recent medical problems (not fully investigated). They did however clear the donor, but then withdrew the donor a few days later after conditioning had already been started. There is no back up donor and a new search was underway. Transplant cancelled.	Not assessable	Definite
2003	CBU	Cord arrived thawed. The cord appears to have been infused. Not yet know whether the patient engrafted	Not assessable	Not assessable
2011	CBU	Dry shipped X-rayed at airport. Transplant delayed due to patient factors therefore product not used yet.	Definitely not	Excluded
2011	CBU	Damage to the overbag, but internal bag undamaged and product uncompromised	Definitely not	Excluded
2011	CBU	Leak between compartments. Used without problems	Definitely not	Excluded
2011	CBU	Leak in the sealing line. No clinical impact	Excluded	Excluded
2011	CBU	Poor viability on thawing. Used as part of a double cord procedure	Unlikely	Unlikely
2011	CBU	Thawed unit on arrival - sent back to CBB. No other unit available and a donor search was reinitiated. The event was thought to be due to bad handling of the dry-shipper in transit. The dry shipper was in good condition	Definite	Definite
unknown	CBU	Clogged and thick cord blood once thawed, new line required, time lost. Engraftment not yet known.	Probably not	Not assessable
2011	DLI	Product X- rayed	Excluded	Excluded
2011	PBSC	Fever following infusion. Bacillus isolated from patient. No pathogens isolated from product. Patient engrafted and well	Not assigned	Unlikely
2011	PBSC	Possible TRALI. Full recovery in patient	Possible	Possible
2011	PBSC	Acute respiratory failure 2 hours after infusion - ?TRALI. Patient death	Not assessable	Possible
2011	PBSC	Xrayed product. Patient engrafted	Unlikely	Excluded
2011	CBU	Fracture in cord blood bag. No product lost	Definitely not	Excluded
2010	BM	Hepatitis B developing in the donor after donation (test negative prior). Patient also became positive for Hepatitis B	Possible	Possible
2011	BM	Bacillus cereus isolated from product (patient became unwell, but bacillus not isolated)	Possible	Possible
2010	PBSC	Delay in transfer of product due to weather conditions. Viability 37%. Patient did not engraft.	Possible	Possible
2010	PBSC	? TRALI	Possible	Possible
2005	CBU	Donor derived myeloproliferative disorder 5 years post transplant (original transplant for AML)	Probable	Probable
2011	CBU	Cord unit arrived thawed. Was not used	Not given	Not assessable
2011	CBU	Positive culture in CBU at TC but not at CBB. Patient well	Possible	Excluded
2004	BM	Donor transmitted CLL. Patient developed CLL 4	Definite	Definite

	S(P)EAR Committee Annual Report - year 2011			
	Document Type:	Annual Report	WG/Committee:	SEAR
	Document Reference:	20120821-SEAR-Annual Report 2011	Other (specify):	
	Version:	2	Approved by:	SEAR
	Drafting Date:		Approval date:	20120821
	Status	Public		
		years following transplant for ALL. CLL clone found in donor pre-donation sample		
2011	CBU	CBU infused with the washing solution. Renal failure developed, but improved	Probable	Probable
2011	BM	Positive bacterial culture in the harvest. Patient died of multiorgan failure, but the same pathogen was not isolated	Definitely not	Possible
2011	PBSC	Discrepancy in pre and post thaw viability. Patient engrafted	Not given	Excluded
2011	CBU	Blood group incorrect. No clinical harm	Not given	Excluded
2011	CBU	CBU bag breached. Product recovered and infused	Definitely not	Excluded
2011	CBU	Poor yield at thaw. Patient engrafted.	Definitely not	Excluded
2011	PBSC	Discrepancy in pre and post thaw viability. Patient engrafted	Not given	Excluded
2011	BM	PRES diagnosed post infusion	Probably not	Unlikely
2011	PBSC	Donor failed to mobilise. 0.73x10 <sup>6</sup> /kg infused. Patient engrafted.	Not given	Excluded
unknown	CBU	CBU arrived thawed. Not infused, but a replacement unit sent the following day	Not given	Excluded
2011	BM	Haemolysis of product which could not be used. Replacement CBU the following day.	Possible	Possible
2011	DLI	Could not collect DLI so patient received a unit of whole blood	Not given	Not assessable
2011	BM	Clots in the product. No harm to patient	Not given	Excluded
2011	CBU	Both units arrived thawed	Definitely not	Not assessable
2008	BM	Incorrect recipient name on product label, other identifiers correct. Cells used for correct patient.	Definitely not	Excluded
2010	CBU	Alarm of data logger flashing when cord received	Not stated	Excluded
2010	CBU	TC says that the aliquots were separate from the unit, CBB says they were attached.	Not stated	Excluded
2010	CBU	Bag compromised on arrival - not used for transplant	Not stated	Not assessable
2010	CBU	Unit was received thawed due to incorrect handling by courier - not used for transplant	Not stated	Not assessable
2011	CBU	Double cord unit 'shocked heart' reaction	Possibly	Possible
2010 (date infusion)	CBU	CBU exploded in the water bath - unit completely lost. 2nd unit was transfused	Definitely not	Not assessable
2010?	CBU	Low viability and post-thaw TNC compared to reported. Non engraftment	Probably	Probable
Unknown	CBU	Low viability and no CFU post transportation. Unit not used	Probably related to transport	Not assessable
Unknown	CBU	Temperature problems during transportation - shipper most likely mishandled. Unit not used	Probably related to transport	Not assessable
2010	PBSC	Donor chromosomal abnormality (XXY) noted on chimerism monitoring.	Definite	Definite
2010	PBSC	Harvest centre performed only 1 day collection despite achieving only 1/4 of the requested cell dose. TC and hub not informed. Donor required a BM harvest later. Patient did not engraft.	Probably	Probable
2010	PBSC	Harvest cryopreserved at harvesting centre. Clots in bag. Arrived with very low cell counts. Patient failed to engraft. Death occurred contributed to by graft failure	Probably	Probable





S(P)EAR Committee Annual Report - year 2011			
Document Type:	Annual Report	WG/Committee:	SEAR
Document Reference:	20120821-SEAR-Annual Report 2011	Other (specify):	
Version:	2	Approved by:	SEAR
Drafting Date:		Approval date:	20120821
Status	Public		

2010	PBSC	Possible TRALI with ITU admission	Possibly	Possible
2011	PBSC	Cell doses and collection volume differed between harvest centre and transplant centre	Definitely not	Unlikely