

NATIONAL MARROW DONOR PROGRAM[®] BE THE MATCH[™]

SHARING OUR PASSION FOR LIFE

COUNCIL MEETING 2013

Subsequent Donations: **One More Time**

John Miller, MD
Willis Navarro, MD

Financial Disclosures – None

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Conflict of Interest Disclosure

We attest that we have no relevant financial, professional, or personal relationship with a commercial interest producing health care goods/services related to this educational activity.

We will not discuss off-label use of commercial products.

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Objectives

1. State common patient situations that warrant a subsequent donation & the rationale for certain product requests.
2. Describe the NMDP approval process of subsequent donation request.
3. Review case studies of complicated subsequent donation requests and ethical issues that may be encountered with these requests

Recipient Considerations

Subsequent Donation Request Situations

Relapse / Recurrence of Disease

Immune Reconstitution

Graft Failure

Post-Transplant Lymphoproliferative Disorder (PTLD)

Insufficient Cell Dose

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

5

Product Request Rationale

TC,
Apheresis

- Relapse
- Mixed chimerism
- Immune Reconstitution

Both patient and donor cells are present

HPC,
Apheresis

- Graft Failure
- Relapse
- Insufficient Cell Dose

HPC,
Marrow

- Graft Failure
- Relapse
- Insufficient Cell Dose

Note: Common terms "T-Cells", "Marrow" & "PBSC" will also be used within presentation.

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

6

Number of Requests by Product per CIBMTR

Original Product	Requested Product	Number 1/1/12 - 12/31/12	Number** 1/1/13 - 8/14/13 Actual / Projected
HPC, Marrow	HPC, Marrow	5	7 / 11
HPC, Marrow	HPC, Apheresis	39	33 / 53
HPC, Marrow	TC, Apheresis	77	66 / 106
HPC, Apheresis	HPC, Marrow	9	3 / 5
HPC, Apheresis	HPC, Apheresis	43	66 / 106
HPC, Apheresis	TC, Apheresis	154	143 / 229
**Mean = 343 days **Median = 175 days		327	318 / 510

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Number that actually Donated by product type per CIBMTR

Original Product	Second Product	Number 1/1/12 - 12/31/12	Number** 1/1/13 - 9/9/13 Actual / Projected
HPC, Marrow	Tubes	1	0 / 0
HPC, Marrow	HPC, Marrow	4	4 / 6
HPC, Marrow	HPC, Apheresis	31	23 / 35
HPC, Marrow	TC, Apheresis	65	45 / 68
HPC, Apheresis	HPC, Marrow	8	0 / 0
HPC, Apheresis	HPC, Apheresis	36	34 / 51
HPC, Apheresis	TC, Apheresis	147	95 / 143
**Mean = 407 days **Median = 222 days		292	201 / 303

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Emergency Subsequent Request?

What is the cutoff dose to determine
Emergency Subsequent Donation
versus **Monitor For Engraftment**?

Dose x10 ⁶ for PBSC x10 ⁸ for Marrow	NMDP MD Action
≥2	Monitor for engraftment x4 wks
1 – <2	Evaluate request
<1	Approve request

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

9

Incidence Rate of Subsequent Donation Request For Inadequate Collections*

Marrow 1 in 500

PBSC 1 in 1000

* Wide statistical confidence intervals given the low frequency of these events;
based on review of Quality Incidents 4/16/12 – 6/30/13 by TMS

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

10

Will this work?
What is Success of Subsequent Transplant?

A chance with but no chance without

No single general statistic

Many variables affect outcome

Reasonable for TC to request subsequent

**NMDP Review &
Approval Process**

NMDP Request & Approval of Subsequent Donation Request



- Submits request & paperwork to Case Management (CM)



- Reviews donor recovery status
- Discusses request with TMS if not recovered

NMDP Request & Approval of Subsequent Donation Request



- **Evaluates**
 - diagnosis
 - disease status
 - indications shared for rationale of subsequent donation request
 - last transplant date
 - previous product cell dose
 - reported donor recovery status

TC Request for Subsequent Donation

F20 PREVIOUS TRANSPLANT HISTORY											
Page 1 of 2											
PATIENT DATA											
Patient name						Patient ID					
Transplant facility						Indication for patient match					
Previous organ						Previous ID					
Is re-transplant diagnosis						Reason for a prior transplant					
						Reasons status at time of initial transplant					
Date of re-transplant						Date of initial transplant					
Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female						Caucasian <input type="checkbox"/> African American <input type="checkbox"/> Other <input type="checkbox"/>					
Current disease status						Transplant group/ID					
Reason for subsequent transplant											
Donor ID						Donor region					
DATA FROM PREVIOUS TRANSPLANT											
Number of previous transplants						Date of last transplant (YYMMDD)					
Manipulation:						Cause					
<input type="checkbox"/> Allogeneic marrow						<input type="checkbox"/> Allogeneic PBSC					
<input type="checkbox"/> Autologous						<input type="checkbox"/> Irradiated					
Source of stem cells for last infusion						Cause of blood					
						Leukemia					
Cells dose administered to recipient						Marrow					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Cells dose conditioning treatment						PBSC					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Old conditioning regimen (bortezomib, etc.)						PBSC					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Old conditioning regimen (bortezomib, etc.)						PBSC					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Was any portion of the stem cell product cryopreserved?						Reason for cryopreservation					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
If Yes, list the cell dose used						Marrow					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
If any portion of the stem cell product was cryopreserved, was it infused?						PBSC					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
If Yes, what was the date of infusion?						Reason for infusion					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Are autologous rescue cells available?						Reason for infusion					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Alternative treatment for patients leukemia/lymphoma						Reason for infusion					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Is there an alternative suitable unrelated donor?						Reason for infusion					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Is there an alternative suitable unrelated donor (not listed above)?						Reason for infusion					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
TRANSPLANT RELATED EVENTS & STATUS											
Event type						Date (YYMMDD)					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Event type						Date (YYMMDD)					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Event type						Date (YYMMDD)					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
Event type						Date (YYMMDD)					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
TRANSPLANT RELATED COMPLICATIONS IN PATIENT											
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Chronic					
<input type="checkbox"/> Yes						<input type="checkbox"/> No					
GVHD (chronic/acute involved)						Acute					

- **Complicated documents**
- **Detailed information**

Pg 1 Data Reviewed

1. Diagnosis
2. Current Disease Status
3. Reason for Request
4. Date of Last Infusion
5. Cell Dose Administered
6. Conditioning Type
7. Rescue / Cryo available?
8. Engraftment / Chimerism

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

15

TC Request for Subsequent Donation

F20		PREVIOUS TRANSPLANT HISTORY	
Page 1 of 3			
PAIENT DATA			
Patient name	Patient ID#		
Referral hospital	Assigned to patient report		
Transplant center	Patient ID#		
	Assigned to clinic report		
CURRENT CLINICAL STATUS OF PATIENT			
The clinical condition of the patient is:			
Is the patient in best or near best overall capacity?		<input type="checkbox"/> Excellent	<input type="checkbox"/> Good
Is the patient in best or near best overall capacity?		<input type="checkbox"/> Fair	<input type="checkbox"/> Compromised
If yes, please check all that apply: <input type="checkbox"/> Unstable <input type="checkbox"/> Stable <input type="checkbox"/> Complex <input type="checkbox"/> Simple			
Is the patient receiving any of the following medication? PLEASE CHECK ALL THAT APPLY			
<input type="checkbox"/> Hematopoietic growth factors		<input type="checkbox"/> Immunosuppressants	<input type="checkbox"/> Antibiotics
<input type="checkbox"/> Other:			
CURRENT TRANSPLANT CONVICTION (Bacterial origin)			
Hepatitis:			
Hepatitis B		Hepatitis C	
If yes, has the patient received any treatment?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, has the patient received any treatment?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, did the treatment result in a cure?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, did the treatment result in a cure?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is the patient receiving any of the following medication?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please check all that apply: <input type="checkbox"/> Unstable <input type="checkbox"/> Stable <input type="checkbox"/> Complex <input type="checkbox"/> Simple			
Is the patient suffering from kidney function abnormalities?			
<input type="checkbox"/> Yes		<input type="checkbox"/> No	
If yes, please check all that apply: <input type="checkbox"/> Unstable <input type="checkbox"/> Stable <input type="checkbox"/> Complex <input type="checkbox"/> Simple			
PREVIOUS HISTORY FOR RECYCLED DONATION			
Has there been any prior or present infectious disease up to or prior to this transplant? <input type="checkbox"/> Yes <input type="checkbox"/> No			
What product was reported? <input type="checkbox"/> Bone marrow <input type="checkbox"/> PBSC <input type="checkbox"/> Cord blood <input type="checkbox"/> Tissue <input type="checkbox"/> Lymphocyte			
What product was reported? <input type="checkbox"/> Bone marrow <input type="checkbox"/> PBSC <input type="checkbox"/> Cord blood <input type="checkbox"/> Tissue <input type="checkbox"/> Lymphocyte			
Has the recipient been infected, please state why:			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
DETAILS PLANNED ON NEW SPY			
Will the patient receive further chemotherapy prior to infusion? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Medication: <input type="checkbox"/> Bone marrow <input type="checkbox"/> PBSC <input type="checkbox"/> Cord blood <input type="checkbox"/> Tissue <input type="checkbox"/> Lymphocyte			
Will the patient receive further chemotherapy prior to infusion? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Medication: <input type="checkbox"/> Bone marrow <input type="checkbox"/> PBSC <input type="checkbox"/> Cord blood <input type="checkbox"/> Tissue <input type="checkbox"/> Lymphocyte			
Will the patient receive further chemotherapy prior to infusion? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Medication: <input type="checkbox"/> Bone marrow <input type="checkbox"/> PBSC <input type="checkbox"/> Cord blood <input type="checkbox"/> Tissue <input type="checkbox"/> Lymphocyte			
Please state the expected response probability for your patient and describe the evidence for your conclusion:			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
PROGNOSTIC PREFERENCE			
Please state for product preference:			
<input type="checkbox"/> Yes <input type="checkbox"/> No			
THIS FORM IS REQUIRED FOR ANY clinical report for enhanced assessment.			
Person completing this form: <input type="checkbox"/> Yes <input type="checkbox"/> No			
Date: 01/11/2018 01:03			
Signature:			

Pg 2 Data Reviewed

1. Clinical Condition
2. Hgb / Platelets
3. Red Cell Dependent?
4. Platelet Dependent?
5. Is a new HCT planned?
6. Reason for preferred product

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Donor Considerations

NMDP Request & Approval of Subsequent Donation Request

Donor Center

- Receives request when NMDP MD does
- Evaluates donor status & discusses concerns with DC MD
- Approaches donor re: subsequent donation request
- Informs CM of donor's decision

Why at the same time?

Time is of the essence for this decision.
Rarely is a request denied.

NMDP Subsequent Donation Policy

Product	Recipient 1	Recipient 2
HPC <ul style="list-style-type: none"> • Marrow • PBSC 	1-2	1-2
T-Cells	1-2	1-2
Total Donations HPC & T-Cells	3 Max 2 HPC	3 Max 2 HPC

Lifetime max for HPC, Marrow donations = 2

**Non-conforming request may be submitted to
NMDP MD for consideration**

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

19

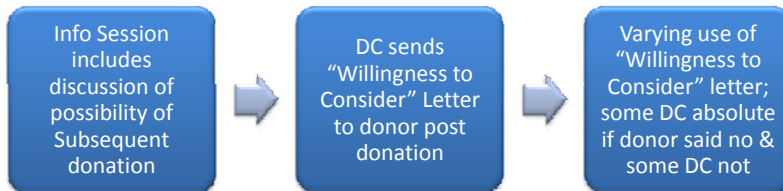
NMDP Subsequent Donation Policy

- Every subsequent donation requires consent
- Donor suitability and eligibility guidelines must be met
- Donor should not be available for a second recipient until at least 1 yr since first HPC or at least 3 yrs since a subsequent HPC
- Donors shouldn't donate HPC for second recipient unless no equally compatible donor is available for second recipient
- Donations for a 3rd recipient not permitted
- Donor must have reported full recovery
- Second PBSC shouldn't be undertaken if donor was a non-mobilizer
- **Non-conforming request may be submitted to NMDP MD for consideration**

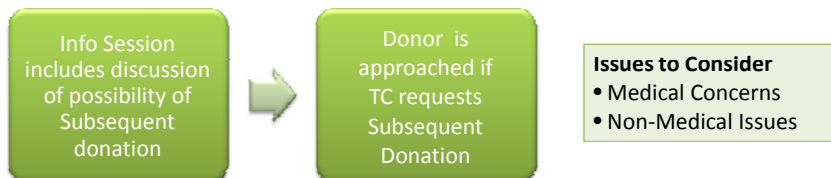
COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Subsequent Donation Considerations

Current Process



Future Process under consideration



COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Issues that Impact Approaching Donor

- Tolerated initial donation process poorly
- **Non-medical issues**
- Caretaking behaviors of DC staff usurping donor decision
- **Donor/Recipient relationship**
- Medically unsuitable
- **Central line placement**
- Multiple requests of same donor

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

22

Suitability Assessment

Original PE <6 months from proposed PBSC/marrow collection	Original PE >6 months from proposed PBSC/marrow collection
<ol style="list-style-type: none"> 1. New Form 700 2. All PE blood work - except Hgb S 3. CXR, EKG, & UA not required 4. Repeat HHSQ 5. Use date of earliest signature on HHSQ as "date of medical evaluation" on Form 700 6. Repeat IDMs if >30 days 	<ol style="list-style-type: none"> 1. New Form 700 2. New PE and <i>Addendum to Physical Examination</i> (F00806) 3. All PE testing (including CXR, EKG, & UA) and all blood work - except Hgb S 4. Enter PE date in STAR Link 5. Repeat HHSQ 6. Repeat IDMs

NOTE:

NMDP MD may deviate from described **suitability assessment** plan in the event of an inadequate initial product collection. Appropriate documentation should be retained in the work-up chart.

T-Cells Suitability Assessment

HHSQ, IDMs, venous assessment & any tests requested by MDs

Eligibility determination & documentation must still be performed for the new product.

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

23

CASE STUDIES

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

24

Case Study #1

Recipient: 42 yo F NHL at International TC

Donor: 38 yo F 5'4" 249 lbs

Total CD34 cells requested 336×10^6

Cell dose administered $12.5 \times 10^6 / \text{kg}$

June 13 PBSC collected

Did not tolerate initial collection well.

Required Vicodin to control pain; four wks to recover & still had some pain off/on


July 2 Subsequent Product Request Received
"The patient did NOT engraft"

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

25

Case Study #1

What product would you request?

- 0%  1. PBSC
- 0% 2. Marrow
- 0% 3. T-Cells

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #1

Would you approach this donor?

- 0% **1. Yes**
- 0% **2. No**

WHAT HAPPENED?

- July 5** Donor approached & immediately said “Yes, I’ll do it!”
Discussed options to improve pain management
Cancelled her vacation plans to donate!
- July 10** Cleared for PBSC
- July 18** **PBSC #2 collected**; tolerated collection well
Total CD34 cells collected 1410.6×10^6
- Sept** Donor recovered 1 wk; waiting for pt update 10/15/13

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #2

Recipient: 55 yo M Myelofibrosis, 80 kg at Domestic TC
Donor: 24 yo F

Total CD34 cells requested 401×10^6
Cell dose administered $1.94 \times 10^6 / \text{kg}$

Sept 12 **Day 1 Filgrastim**
Reports scratchy throat & fever; MDs believe viral; TC informed

Oct 2 **PBSC collected & cryopreserved**
24 L over 6.5 hours

Oct 5 **Product infused**

Oct 17 **Subsequent Product Request Received**


“No engraftment; clinical status good; red cell/platelet dependent”
Alternative suitable URD identified

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

28

Case Study #2

What product would you request?

- 0%  1. PBSC
- 0% 2. Marrow
- 0% 3. T-Cells

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #2

Would you approach this donor?

- 0% 1. Yes
- 0% 2. No

WHAT HAPPENED?

- Oct 18** Donor approached; agrees to donate
- Oct 29** Filgrastim starts with minimal symptoms
- Nov 2** **PBSC #2 collected;** CD34 cells collected **285.1×10^6**
- Dec 12** Recipient engrafted; doing well; to be discharged soon
- Feb 17** Recipient death reported d/t treatment-related complications

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #3

Recipient: 10 yo M with Fanconi anemia
Donor: 44 yo F

May 2011 PBSC collected

May 2012 Donor and Recipient meet & establish close relationship

Aug 2013 Donor reports she had tick bite; contracted Lyme's and Babesiosis; recovered w/o complications

Babesiosis is medical deferral due to possible transmission of disease.

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

31

Case Study #3

Would you approach this donor, if needed?

0% **1. Yes**

0% **2. No**

WHAT HAPPENED?

Aug 2013

DC asks input from NMDP MD who recommends that donor be removed from Registry but remain available for evaluation of subsequent donation should her recipient require one.

- ✓ **Primary vs Subsequent Donation**
- ✓ **Donor and Recipient Relationship**

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #4

Recipient: F b 1986 CML

Donor: F b 1979

May 2003 Marrow

Long recovery; hematoma w/ pain & numbness requiring ongoing pain meds; doesn't report recovery until spring 2004

June 2006 Whole Blood collected

Donor knew of pending request; had been in touch with recipient

May 2012 T-Cells requested for mid-July

Donor is very willing but is currently being treated for **ectopic pregnancy** & has received 2 doses of **methotrexate**; may eventually need surgery

DC contacts NMDP MDs to ask

-Should she be TU'd? How long? Can she ever donate?

Case Study #4

WHAT HAPPENED?

May 2012 NMDP MD recommends

- TU until condition resolved
- Monitor HCG levels
- Inform TC of medical issue requiring assessment

Jun 2012 Donor notifies the DC that HCG is now normal; NMDP MD says donor is acceptable to proceed

Jul 2012 T-Cells collected

Sep 2013 10 yr recipient report – complete remission

Case Study #5

Recipient: #1 M b 1951 CLL
 #2 F b 1978 NHL at International TC

Donor: M b 1955

Apr 2004 Donated PBSC #1 for Recipient #1

Feb 2006 Donated T-cell for Recipient #1

Aug 2007 Recipient #1 death reported

Nov 2012 Donated PBSC #2 for Recipient #2

Day 4 dose reduced d/t severe HA

Total CD34 cells requested 220×10^6

Cell dose administered $4.8 \times 10^6 / \text{kg}$

Mar 2013 Subsequent product request received

Engrafted; 100% donor; acute GVHD resolved; WBC 1.5;
 Neut 0.8; Lymph 0.2; platelet & RBC dependent

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

35

Case Study #5

What product would you request?

- 0%  **1. PBSC**
- 0% **2. Marrow**
- 0% **3. T-Cells**

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #5

Would you approach this donor?

0% **1. Yes**

0% **2. No**

Product	Recipient 1	Recipient 2
HPC Marrow or PBSC	1-2	1-2
T-Cells	1-2	1-2
Total Donations HPC & T-Cells	3 Max 2 HPC	3 Max 2 HPC

Lifetime max for **HPC, Marrow** donations = 2

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #5

WHAT HAPPENED?

Mar 14 NMDP MD approves to approach

Mar 28 Cleared for PBSC

Apr 4 **PBSC #3 collected**

First collection ends at 16L w/ interface problems; new machine primed; NMDP MD approves to cont (if platelets >60K) to collect additional 6L over original 18L to try to obtain cells; donor tolerating collection well.

Bag #1 CD34 cells collected 157.7×10^6

Bag #2 CD34 cells collected 224.9×10^6

May 4 Donor reports full recovery; HA resolved

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

38

Case Study #6

Recipient: F b 1954 AML
Donor: M b 1985 5'4" 135lb

Cell Dose Requested **293.5×10^6**

Cell Dose Administered **$<1 \times 10^6 / \text{kg}$**

Pre-apheresis WBC 28.7×10^9 ; pre-apheresis CD34+ 0.11%; abs CD34+ 31.57

Oct 19 **Cleared for both products**

Hgb 12.6; Hct 39.6; MCV 72; MCH 22.8; RDW 17.6 MD notes *"frequent blood donor; most recent donation 1 mo ago; likely Fe deficient"*

Nov 15 **PBSC collection 24L collection**

Post-collection platelets 65K; AC MD recommends to wait until platelets >100K before considering subsequent collection

Dec 5 **Recipient update**

Recipient is +15 day, clinically well; afebrile, transfusion dependent; WBC 0.3; TC wants to wait and watch

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

39

Case Study #6

Dec 29 **Subsequent product request received**
"Persistent disease"

Dec 31 **Donor reports full recovery**

What product would you request?

- 0% → **1. PBSC**
- 0% **2. Marrow**
- 0% **3. T-Cells**

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #6

Would you approach this donor?

0% 1. Yes

0% 2. No

WHAT HAPPENED?

Jan 2013 Consented to donate but Medically Deferred

- Donor labs repeated: WBC 3.3; Hgb 12.9; MCV 72.6; MCH 22.2; Neu Abs 1.90; Iron 39; Fe Binding Capacity 452; % Sat 9
- Donor deferred by AC d/t iron deficiency and abn labs

Mar 2013

Donor #2 identified through co-op registry; PBSC collected

May 2013

TC reports recipient is disease-free and doing well

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #7

Recipient: F b 1974 MDS

Donor: M b 1961

Cell Dose Requested 288 x 10⁸ / kg

Cell Dose Administered 0.65 x 10⁸ / kg

Nov 23 PE for PBSC reveals sickle cell pos & platelets 144K; cleared as marrow-only; TC accepts marrow

Dec 19 Donor notifies DC of Dengue fever diagnosis

Dec 29 Marrow collection following donor's recovery

Apr 19 Subsequent product request received

"disease progression; chimerism 60% donor & 40% recipient"

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

42

Case Study #7

What product would you request?

- 0% 1. PBSC
- 0% 2. Marrow
- 0%  3. T-Cells

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #7

Would you approach this donor?

- 0% 1. Yes
- 0% 2. No

WHAT HAPPENED?

May 8	Cleared for T-Cells ; plts 137K
May 10	T-Cells collected w/ femoral central line AC collects 18L; not 23L as requested by TC
May 17	Donor fully recovered; central line site healing
Dec 2012	Recipient death reported d/t disease relapse

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #8

Recipient: M b 1945 AML

Donor: M b 1995

Cell Dose Requested **1,106 x 10⁶**

Cell Dose Administered **5.2 x 10⁶ / kg**

Mar 12 Declines PBSC; consents to marrow only;
TC accepts product change
Misses PE appt twice; difficult to contact

Apr 8 **Marrow collection**

Reports hip pain 3 wks post collection with bruising

Jul 21 **Subsequent product request received**

"Marrow with cytogenetic relapsed disease"

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #8

What product would you request?

- 0% **1. PBSC**
- 0% **2. Marrow**
- 0%  **3. T-Cells**

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #8

Would you approach this donor?

0% 1. Yes

0% 2. No

WHAT HAPPENED?

Jul DC attempts to contact donor multiple times.
Finally he returns call - he is not interested in donation.
He never told his parents that he donated marrow.
He is living at home now during summer break.
He is sure his family will not be supportive.

Sep Recipient death reported

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Case Study #9

Recipient: M b 1963 MM

Donor: F b 1962

Cell Dose Requested **620 x 10⁶**

Total CD34+ cells collected **845 x 10⁶ / kg**

June 14 **PBSC collection**

Required central line; very poor venous access

July 2 TC submits research request to participate in study to create cell line for possible treatment of post-transplant viral infections BUT this **requires T-Cells collection**

Cells may never be used by this recipient.

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

48

Case Study #9

Would you approach this donor?

- 0% 1. Yes
- 0% 2. No

WHAT HAPPENED?

DC discusses request with NMDP MD who determines that donor risk of central line is too great to allow collection with low potential of recipient use; donor is withdrawn from study

Aug 12

Donor informed recipient engrafted & has been discharged; donor states she would be *“happy to donate any product needed in the future...”*

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE

Summary

- Stem cell transplantation is a multifaceted medical treatment.
- A subsequent donation request may present complex practical, logistical, and ethical considerations.
- A subsequent donation may be an integral component in providing the optimal treatment regimen.

COUNCIL MEETING 2013: SHARING OUR PASSION FOR LIFE