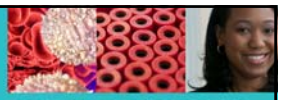

CREATING TOMORROW'S SOLUTIONS, TOGETHER

PREPARING THE TRANSPLANT COMMUNITY TO SERVE EVERY PATIENT IN NEED.

2012 COUNCIL MEETING

Testing, Testing, 1-2-3: **Extended Medical Tests and Donor Evaluation**

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Conflict of Interest Disclosure

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

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

Objectives

1. Discuss the purpose and process of extended medical evaluation in the assessment of unrelated stem cell donors.
2. Describe ethical issues that may arise within the context of donor evaluation.
3. Identify situations where extended medical tests can facilitate or impede donor assessment.

Who is here today?

0% 1. Donor Center
0% 2. AC/CC
0% 3. Coordinating Center (NMDP staff)
0% 4. Transplant Center
0% 5. International (DC/AC/CC/TC)
0% 6. Other

What is your background?

0% 1. Physician / PA / NP
0% 2. Nurse
0% 3. Biology / Science
0% 4. Social Sciences
0% 5. Other

Have you had a donor who required Extended Medical Testing?

0% 1. YES

0% 2. NO

Purpose of Donor Assessment

Evaluate an individual's suitability to serve as a donor of marrow and/or PBSC

Donor Safety	Recipient Safety
• Unrelated volunteer • Risks of donation process	• Infectious or genetic disease transmission • Product quality

What is **Extended Medical Testing?**

Evaluations (e.g., tests, medical consults) performed following routine donor assessment (PE and tests) in order to determine donor suitability

Performed to further evaluate clinical findings that may be detected on routine donor assessment

Why Perform **Extended Medical Testing**?

Better evaluation of donor risk

- Provides more information that can be used to better determine whether the identified medical issue confers greater than usual risk

May be performed to obtain a better assessment of recipient risk

Process for
Extended Medical Testing

PE

- AC/CC MD review PE results & determine that additional testing/evaluation is required

Request

- DC initiates Form F00253, *Extended Medical Testing Request*, listing requested tests/ evaluations, reasons needed, and costs
- DC submits to CM before any testing or appointments occur

Process for
Extended Medical Testing

Review & Approval

- If <$500, CM reviews/approves
- If >$500, CM Manager reviews/approves
- If questions, CM turns to NMDP MDs for guidance
- NMDP MD may request details to understand rationale for tests
- If approved, CM informs DC & NMDP Finance
- If declined, CM informs DC

Process for
Extended Medical Testing

Testing

- Extended Tests and/or consults performed

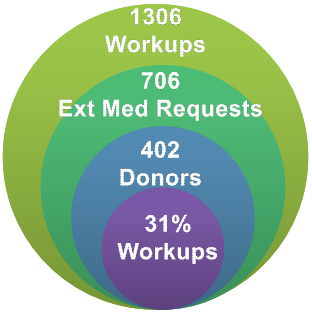
Eval

- AC/CC/DC MDs evaluate new information

Outcome

- More tests/consults requested
- Cleared; proceed to collection
- Not Cleared; referred to personal MD

Extended Medical Testing Utilization: 2011



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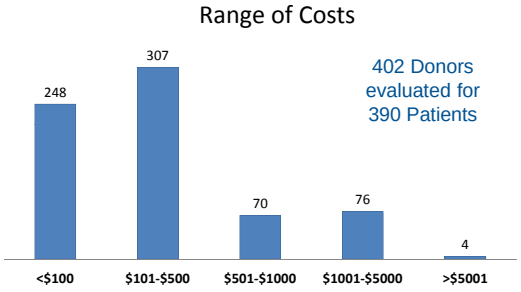

Extended Medical Testing Utilization: 2011

1. Venipuncture / Lab Draws
2. Cardiology Evaluations
3. Radiology (CXR, CT, US)

Least Expensive	• LDH $1.90
Most Expensive	• Abd CT Exam $7,282.87

Issues to Consider:
The Donor Perspective

Is the donor becoming a patient?

- Some tests/evaluations are beyond the scope of donor assessment – require appropriate testing, counseling and interpretation of results (e.g., sleep apnea evaluation)
- Treatment of medical conditions so donor can donate (e.g., HTN, UTI)
- Clinical judgment important – confirming absence or diagnosing a medical condition (e.g., cardiac evaluation)

Issues to Consider:
The Donor Perspective

Are we testing the donor into suitability?

- Performing multiple tests until NMDP guidelines are met (e.g., platelets $\geq$150)

Is the test as or more risky than donation itself?

- Certain evaluations/procedures associated with prohibitive risks (e.g., bone marrow biopsy)

Issues to Consider:
The Donor Perspective

Is this possible coercion?

- Donors without health insurance – will provision of additional medical evaluation/ care coerce donors to donate and undermine risks

Issues to Consider:
DC/AC/CC MD's

Assessment of donor risk

- MD's frequently evaluate both related and unrelated donors – possible willingness to accept higher risk of URDs
- Individual variation in expertise and experience (e.g., evaluating EKG's)

Issues to Consider:
The Recipient/TC Perspective

Transplant delay

- If another donor available, transplant can be performed in a more timely manner vs. pursuing extended testing

$$$

- Costs are passed on to recipients/TCs

Issues to Consider:
The NMDP Perspective

Advocate for both Donor & Recipient

Stewards of Limited Resources

Summary

- Extended Medical Testing has an important role in assessment of donors where more information is required to judge donor suitability
- There are several donor and recipient issues to consider
- Ultimate determination of donor suitability is based on medical judgment

CASE STUDIES

Case Study #1

Recipient: 21 y F; ALL
Donor: 31 y M requested for PBSC

HHSQ at WU: #53 yes = MSM; last contact 1 yr ago; CM/TC notified

PE: normal **IDM:** negative

Labs #1:
Hgb 14.7; Hct 43.5
WBC 9.3; Neu% 27.6; **Lymphs % 65.7 (45.5)**;
Mo% 4.4; Ba% 1.1; **Lymphs # 6.1(4.8)**

12

Case Study #1

MD Note:
"Reactive lymphocytosis, suggesting the presence of … active viral infection…possibility of active CMV or EBV infection… We can repeat the hemogram in 2-4 weeks to confirm resolution of the active infection."

EXTENDED TESTING REQUEST: Repeat CBC

Case Study #1

Should this request for Extended Medical Testing be approved?

0% **1. Approve**
0% **2. Not Approve**

Case Study #1

DECISION: Approved
RATIONALE: Likely viral infection

WHAT HAPPENED?

- **Labs #2: WBC 12.4 (10.6)**; Neu% 21; **Lymph% 73 (45.5)**; Mo% 4.2; Eo% 0.7; **Lymph# 9.1 (4.8)**
- Plan to repeat CBC in 2 wks w/ flow cytometry
- Flow Cytometry = *lg granular lymphocytes with an aberrant phenotype; cannot exclude possibility of indolent lymphoproliferative disorder*

Deferred; referred to PCP; TC still searching

Slide 25

n2 Was a busy slide – cut down the not so relevant parts of the MD note
nmajhail, 10/24/2012

Case Study #2

Case Management to DMS:

- Tooth abscess found at PE
- Potential donor does not have health insurance
- AC will not clear with the existing tooth infection

EXTENDED TESTING REQUEST:

Dental Assessment & Possible Dental Surgery

Case Study #2

Should this request for Extended Medical Testing be approved?

0% **1. Approve**

0% **2. Not Approve**

Case Study #2

DECISION: **Not Approved**

RATIONALE:

- Possible ethical issue with paying for treatment of a donors health issue to “make” him suitable
- Possible coercion?
  - Is he agreeing to donate because he finally will get his tooth treated?
  - Will he be honest in his health information in order to get this treatment?

Case Study #3

Recipient: 60 y M; AML

Donor: 48 y M requested for PBSC

PE: Seen by PCP earlier in year; sleep study had been recommended but had not yet been performed

DC to Case Management to DMS:

- *Donor really wants to do marrow*
- *Will consider PBSC if marrow ruled out due to sleep apnea*
- *TC is struggling to find a donor*

EXTENDED TESTING REQUEST: Sleep Study

Case Study #3

Should this request for Extended Medical Testing be approved?

0% **1. Approve**

0% **2. Not Approve**

Case Study #3

DECISION: Not Approved

RATIONALE:

- Cannot conduct a volunteer's needed health assessment
- Establishes "medical relationship"
  - More involved than only the sleep study
  - Who is responsible for determining need for C-PAP, ordering machine, evaluating treatment & ongoing assessment?

WHAT HAPPENED?

TC cancelled all searches; poor pt status

Case Study #4

Recipient: 56 y M; AML
Donor: 22 y F requested for PBSC
UA: abnormal; indicates urinary tract infection

DC to Case Management to DMS:
DC MD wants the donor to take antibiotic for 3 days and wait for results. Wanted to notify you for reimbursement of the medication.

EXTENDED TESTING REQUEST:
Antibiotic x 3 days; repeat UA/UC

Case Study #4

Should this request for Extended Medical Testing be approved?

0% **1. Approve**
0% **2. Not Approve**

Case Study #4

DECISION: **Approved**
RATIONALE:
- Treating donor as patient but localized infection
- Should this have been approved???

WHAT HAPPENED?
PBSC collected late September

Case Study #5

Case Management to DMS MD:

- Breast mass detected upon physical exam

EXTENDED TESTING REQUEST:

Breast Ultrasound

Case Study #5

Should this request for Extended Medical Testing be approved?

0% **1. Approve**

0% **2. Not Approve**

Case Study #5

DECISION: **Not Approved**

RATIONALE:

- Cannot pay for a volunteer's needed health assessment
- Donor is becoming the patient – evaluation and treatment of a breast mass beyond scope of donor wkup

WHAT HAPPENED?

- DC performed U/S on their own & donor cleared
- PBSC successfully collected
- **Donor was a 20 y M - but DMS did not know this!**

Case Study #6

Recipient: 60 y F; AML

Donor: 37 y M requested for PBSC; changed to marrow-only d/t low plts

PE: WBC 3.9; Hgb 13.9; Hct 44.9; plts 121

EXTENDED TESTING REQUEST #1:
Repeat CBC & repeat EKG

Platelets remain <150

EXTENDED TESTING REQUEST #2:
Bone Marrow Biopsy

Case Study #6

Should this request for Extended Medical Testing be approved?

0% **1. Approve**

0% **2. Not Approve**

Case Study #6

DECISION: DC MD did the test without DMS MD input

RATIONALE for NOT APPROVING:

- Cannot pay for a volunteer's needed health assessment
- Invasive and painful procedure that should not be performed on "healthy" volunteer
- Donor is becoming the patient

WHAT HAPPENED?

- **BM Biopsy**: *mildly hypocellular marrow showing maturing trilineage hematopoiesis. Diagnostic features of involvement by MDS or marrow infiltrative process not seen*
- DC MD willing to clear; requests biopsy be shared w/ TC
- TC declined and moved to CBUs; transplant 6/12

Case Study #7

Recipient: 50 y F; CLL
Donor: 51 y F requested for PBSC
PE: depression, stable; distant history basal cell CA
LABS #1: Hct 45; plts 455 (415)
EXTENDED TESTING REQUEST #1: Repeat CBC & ferritin
LABS #2: plts 448 (400); ferritin 40 WNL

EXTENDED TESTING REQUEST #2: abdominal u/s to assess for hepatosplenomegaly; Jak-2 mutation analysis and PCR for t(9,22); if negative, then bone marrow biopsy

Case Study #7

Should this request for Extended Medical Testing be approved?

0% **1. Approve**
0% **2. Not Approve**

Case Study #7

DECISION: **Approved with Modification**
- NMDP MD discussed with CC MD
- Start with Jak-2 and t(9:22) only
- If normal, then able to clear; if not normal, refer to PCP

RATIONALE:
- If tests normal, likelihood of myeloproliferative disorder is low

WHAT HAPPENED?
All tests NORMAL. Successful marrow collection.

Case Study #8

Recipient: 3 y F; Beta Thalassemia Major

Donor: 39 y F requested for marrow

HHSQ: HTN, stable; psoriasis = marrow-only

EKG: sinus rhythm; premature atrial complexes with aberrant conduction; T wave abnormality; consider anterolateral ischemia

MD Notes re: EKG: no Q-waves are visible; mild T-wave abn with inverted T-waves in the lateral leads suggesting old anterior lateral ischemia

EXTENDED TESTING REQUEST: Basic Stress Test

"rule out any cardiac abnormalities since she does have history of HTN and is sl overweight"

Case Study #8

Should this request for Extended Medical Testing be approved?

0% **1. Approve**

0% **2. Not Approve**

Case Study #8

DECISION: **Approved**

RATIONALE: While possibly overcautious testing, request is for marrow with use of general anesthesia.

WHAT HAPPENED?

- NORMAL exercise stress echo
- Successful marrow collection

Case Study #9

Recipient: 46 y M; Severe Aplastic Anemia
Donor: 47 y F requested for marrow & cleared by CC

PE & HHSQ: Normal

LABS: WBC 11.8 (9.8); Neuts % 23.8; Lymphs % 67.5 (50); Lymphs # 8 (4.2)

EXTENDED TESTING REQUEST by DMS MD:
Repeat CBC with flow cytometry

Case Study #9

Should this request for Extended Medical Testing be approved?

0% **1. Approve**
0% **2. Not Approve**

Case Study #9

DECISION: **Approved**
RATIONALE: Medical judgment

WHAT HAPPENED?
WBC 13.2 (10.5); significantly abn differential
Flow Cytometry: *"Monoclonal B lymphocytes with a chronic lymphocytic leukemia-like immunophenotype"*

- **Donor deferred and referred to PCP**
- **TC cancelled request while tests were still pending**

Medical Judgment Process

DATA

HHQ
IDMs
H&P
Labs
CXR
EKG
UA

ANALYSIS

Clinical Correlation
Medical Experience

- Accept for both products
- Accept for 1 Product-only
- "Extended" testing
- Temporary Unavailable
- Medically Defer
- Treat & Wait

CONCLUSION

Keeping in mind assessment goals:
Safe donation & Safe product

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