

Blood and Marrow Transplantation: Donor Safety

Introduction/Problem

- FACT (Foundation for the Accreditation of Cellular Therapy) and the FDA have multiple regulations regarding donor evaluation.
- All donors must be assessed for safety for the recipient. Examples include: malignancy, history of immunological/inflammatory conditions, or infectious diseases.
- Donor's also must be assessed for any issues that might harm the donor during the procedure. Examples include: Cardiac disease, splenomegaly, or a history of thrombotic events.
- Upon auditing the donor evaluation process, it was identified that while we were compliant with the recipient safety evaluation, we were not with the donor safety evaluation, only having 60% compliance.

Aim/Goal

To be 100% compliant with the donor safety evaluation, and to communicate any issues to the Apheresis Team as per FACT regulations.

The Team

- Clinical BMT Program: Gosia McMasters, MD; James D. Levine, MD; Robin Joyce, MD; David Avigan, MD; Jamie Mortellite, NP; Denise Cummings, RN Transplant Coordinator; Lauren O'Malley, RN Transplant Coordinator; Kathy Moriarty, BMT Program Manager
- Infusion/Apheresis: Ayad Hamdan, MD; Theresa Normile, RN, Nurse Director

The Interventions

- SOPs and consents were rewritten to be compliant with all FACT required evaluation steps. This included a donor evaluation SOP for allogeneic, autologous, and research donors.
- Forms and macros for charting were designed to facilitate the donor evaluation compliance process.
- Patient rounds were instituted in the apheresis department where every patient/donor being collected is discussed, including donor safety issues using a new form that was created for this process that must be signed by both the BMT Attending MD and the Apheresis Attending MD.

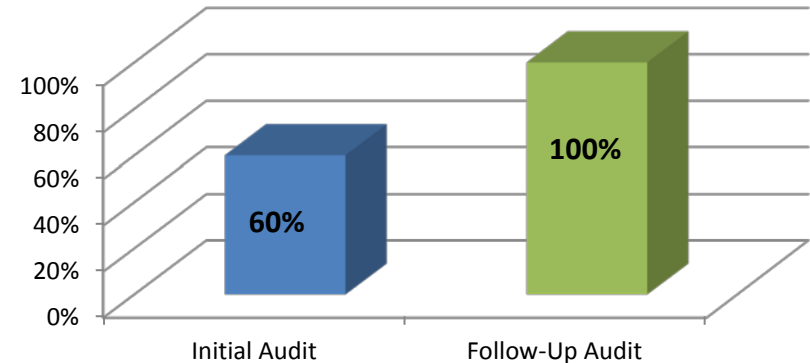
- A few sample questions:

Donor Safety Evaluation	
12. <input type="checkbox"/> Yes <input type="checkbox"/> No	Does the patient have a risk for hemoglobinopathies?
13. <input type="checkbox"/> Yes <input type="checkbox"/> No	Does the patient have a risk for thrombotic events?
14. <input type="checkbox"/> Yes <input type="checkbox"/> No	Is the patient on antiplatelet or anticoagulation medications? (Typically anticoagulant is held prior to collection for line placement)
15. <input type="checkbox"/> Yes <input type="checkbox"/> No	Does the patient have splenomegaly?
16. <input type="checkbox"/> Yes <input type="checkbox"/> No	Does the patient have any specific risk factors making the placement of a central line problematic? Why?

Results/Progress to Date

Donor Safety Evaluation Compliance

From initial audit to post implementation of corrective action plan



Lessons Learned

- New and revised SOPs were not sufficient to effect necessary change.
- The new process required a change in culture and behavior by very busy clinical physicians and nurse practitioners.
- Multiple tools were required to facilitate change such as forms and macros.
- These tools resulted in compliance, but more importantly, the notes now reflect:
 - A common language providing structure and objective criteria
 - Increased specificity
 - Concrete rationale for accepting or deferring a donor
 - Covers all safety concerns for both donor and recipient
 - Provides pertinent education points to the provider and potential donor

Next Steps

- This process will continue to be audited to ensure compliance.
- All involved departments will need to review the new process to see if it can be improved.

For more information, contact:

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