

Path of a Product Through the Workup Process

Susie Sturbaum, Be The Match

Jeni Newman, Be The Match

Disclosures

The following faculty and planning committee staff have no financial disclosures:

Name	Institution
Susie Sturbaum	NMDP / Be The Match
Jeni Newman	NMDP / Be The Match
Jaime Santi	NMDP / Be The Match

Learning objectives

At the conclusion of this session, attendees will be able to:

- Explain the rationale behind critical steps in the product pathway from workup request to collection.
- Analyze ways to effectively facilitate delays that can impact the product pathway.

Our patient



TC Submits the Workup Request

Donor Workup Request

NMDP Recipient ID: 123-456-7 TC Code: 599
International or NMDP Donor ID: 1234-5678-9

1. Recipient Information
1.1. Current diagnosis: AML
If acute leukemia, CML or SAA, complete the following:
a. For AML, ALL, or other leukemia, indicate disease stage (check one) and number of remissions:
☐ Primary induction failure ☒ Complete remission ☐ Relapse ☐ Induction therapy in progress
b. For CML, indicate the current status of the leukemia (check one)
☐ Chronic phase ☐ Accelerated phase ☐ Blastic phase
c. For Severe Aplastic Anemia, has recipient been transfused?
☐ Yes ☐ No
1.2. Classify workup based on patient clinical condition:
☒ Standard ☐ Urgent

2. Stem Cell Choice
2.1. First Choice
☐ Marrow → complete section 4
☒ PBSC → complete section 5
2.2. Second Choice (Must Select One)
☐ Marrow → complete section 5
☒ PBSC → complete section 5
☐ None

3. Pre-Collection Samples
Do not include samples related to a TC research study that requires NMDP IRB approval. Instead, complete the Request for NMDP Donor to Participate in a Research Study form.
3.1. Do you require pre-collection samples to be drawn?
☒ Yes ☐ No
3.2. Pre-Collection blood samples: 50 ml is the maximum volume that can be requested.
☒ Yes ☐ No
NOTE: For non-U.S. donors, the maximum volume is 35 ml.
10 ml Red Top (No Anticoagulant) 10 ml Yellow Top
10 ml Red Top (Sodium Heparin) 10 ml Purple Top
10 ml Green Top (Sodium Heparin)
Pre-Collection Sample Shipping Information
Attn/Name: Sally TC Coordinator
Center Name: The University of Be the Match
Address Line 1: 500 Be the Match Lane
Address Line 2: _____
City, State, Province: Minneapolis, MN
Zip code, Country: 55401
Telephone: 763-657-9309
3.3. Specify when samples should be collected: (optional) at PE

Donor Workup Request

NMDP Recipient ID: 123-456-7 TC Code: 599
International or NMDP Donor ID: 1234-5678-9

4. Marrow Collection
4.1. Length of patient's preparative regimen in days: _____
4.2. Specify number of nucleated cells below:
1. Nucleated cells per kg (uncorrected): _____ x 10⁸/kg
2. Recipient weight: _____ x _____ kg
3. Total nucleated cells for recipient: _____ x 10⁸
4. Nucleated cells for quality assurance: _____ x 10⁸
5. TOTAL nucleated cells requested: _____ x 10⁸
4.3. Enter at least one proposed collection and corresponding donor clearance dates:

	Proposed Collection Date (m/m/yyyy)	Clearance needed by (m/m/yyyy)
First Choice - Required		
Second Choice (Optional)		
Third Choice (Optional)		

4.4. Marrow collection within the NMDP network must be aspirated, filtered and mixed with heparin in quantities sufficient to prevent coagulation. Does your transplant center require additional anticoagulant to be added to the marrow either during or after the aspiration? ☐ No ☐ Yes
a. If yes, specify the anticoagulant including the units, ratio or amount as appropriate:
Anticoagulant: _____ Amount or Ratio: _____
4.5. Specify marrow transport conditions (Select one): ☐ Room Temperature ☐ Cooled

5. PBSC Collection
5.1. Length of patient's preparative regimen in days: 9
5.2. Specify number of desired CD34+ cells:
1. CD34+ cells per kg: _____ 7.00 x 10⁶/kg
2. Recipient weight: _____ x _____ kg
3. Total CD34+ cells for recipient: _____ 420.0 x 10⁶
4. CD34+ cells for quality assurance: _____ 10.0 x 10⁶
5. TOTAL CD34+ cells requested: _____ 430.0 x 10⁶
Reminder: PBSC transport condition is cooled.
5.3. Enter at least one proposed collection and corresponding donor clearance dates:

	Proposed Collection Date 1 (Required) (m/m/yyyy)	Proposed Collection Date 2 (Optional) (m/m/yyyy)	Clearance needed by (m/m/yyyy)
First Choice - Required			
Second Choice (Optional)			
Third Choice (Optional)			

When CD34+ counts are not available, the Apheresis Center collects based on recipient weight as outlined below:

- Recipient weight < 30kg: One 12-liter Apheresis procedure performed.
- Recipient weight 30 – 45kg: One 15-liter Apheresis procedure performed.
- Recipient weight 46 – 55kg: One 18-liter or two 12-liter Apheresis procedure(s) performed.
- Recipient weight 56 – 65kg: One 22-liter or two 12-liter Apheresis procedure(s) performed.
- Recipient weight > 65kg: One 24-liter or two 12-liter Apheresis procedure(s) performed.

Document Number: F00475 Revision 4.0
National Marrow Donor Program®
Fax completed form to NMDP Search Coordinating Unit at 612-627-5810
Page 2

Donor Workup Request

NMDP Recipient ID: 123-456-7 TC Code: 599
International or NMDP Donor ID: 1234-5678-9

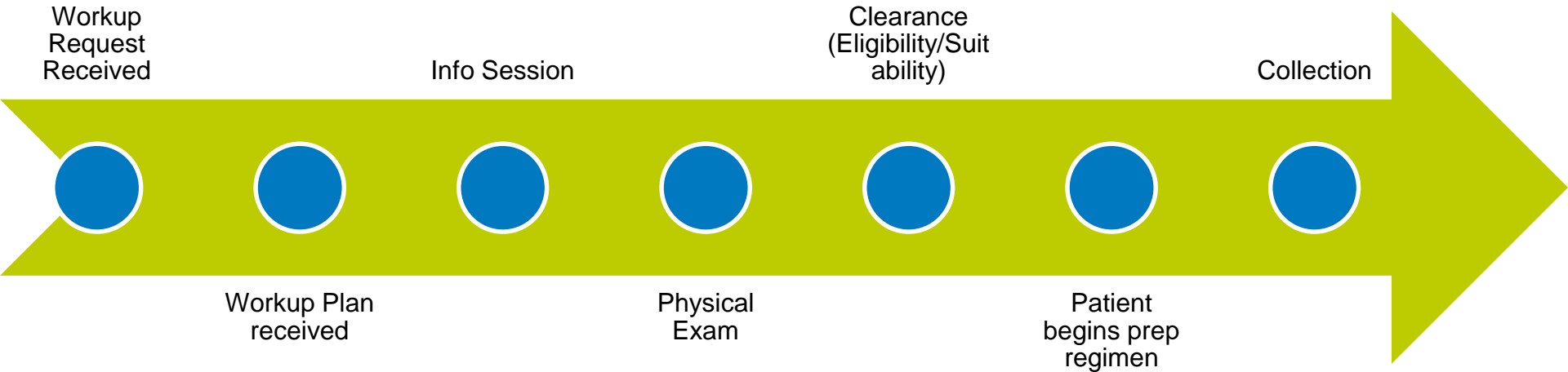
6. Peripheral Blood Collection Samples
Minimum of 10 ml of donor peripheral blood must accompany each product collected (used for the type of tube(s) required by the transplant center).

	Day 1 (PBSC only)	Day 2 (PBSC only)	Product
(No Anticoagulant)	10 ml	10 ml	10 ml
(Sodium Heparin)	10 ml	10 ml	10 ml
(EDTA)	10 ml	10 ml	10 ml
enter: Fax CD34+ results to the following number			
Designated Complete:			
Designated above, I verify that the ABO type, degree of HLA match, compatibility testing and disease results are acceptable to proceed with stem cell collection for above patient.			
Completed By: _____ 09/18/2017 (m/m/yyyy)			
Ordering Physician: _____ Johnny Doctor			
Information for completing the product tag which will become part of the shipment must be attached to each product bag.			
Separated from the courier, NMDP Standards require that Transplant product be provided below onto the product tag.			
Maggie Lab Technician			
The University of Be the Match			
500 Be the Match Lane			
Minneapolis, MN 55401			
657-9309			
Search Coordinating Unit at 612-627-5810			

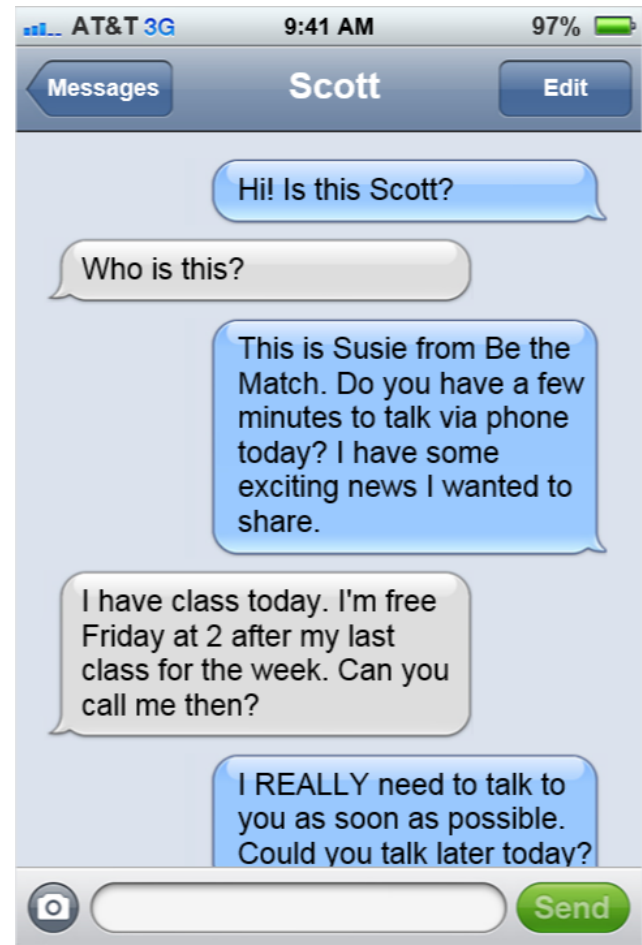
Our donor



Path of a Product



Outreach to the donor



Can't do requested dates



What Would You Do?



Confirm possible availability with the AC.

Immediately go the CM/TC to find out what they want next?

Check w/ the donor to confirm what dates he could do?

Date Negotiation





Challenges

- Capacity at local AC/CCs
- Scheduling w/ donor
- Family dynamics
- Finances
- Transportation
- Weather



Resources

- Other network centers (travel)
- Offer letters to professors/advisors
- Donor Services Liaisons
- AC/CC Liaisons

Workup Plan

Dear Transplant Center,

The dates indicated below have been verified by the donor and AC/CC. All dates are indicated as MM/DD/YYYY.

10/08/2017
Form Submitted Date

Section 1 – Donor Center completes the following information

Donor ID#			Recipient ID#		
DC#		TC#		Product Type:	
AC/CC#		City:			State:

Section 2 – Donor Center completes the following information

DC Proposed Collection Dates

Info Session:		Physical Exam:	
Pre-Collect Draw:		N/A <input type="checkbox"/>	
IDM Draw 1:		IDM Draw 2:	
			N/A <input type="checkbox"/>
(Complete date after receiving prep date.)			
REMINDER: schedule 12 or greater days before prep if possible.			
Estimated Clearance:		Estimated Eligibility:	
Filgrastim Start:		N/A <input type="checkbox"/>	
Collection Day 1:		Collection Day 2:	
			N/A <input type="checkbox"/>

DC Comments:

Section 3 – CM or TC completes the following information

TC Acceptance of Dates ☐ OR TC New Proposed Date(s) ☐

Patient Prep:		Infusion:	
Collection Day 1:		Day 2:	
			N/A <input type="checkbox"/>

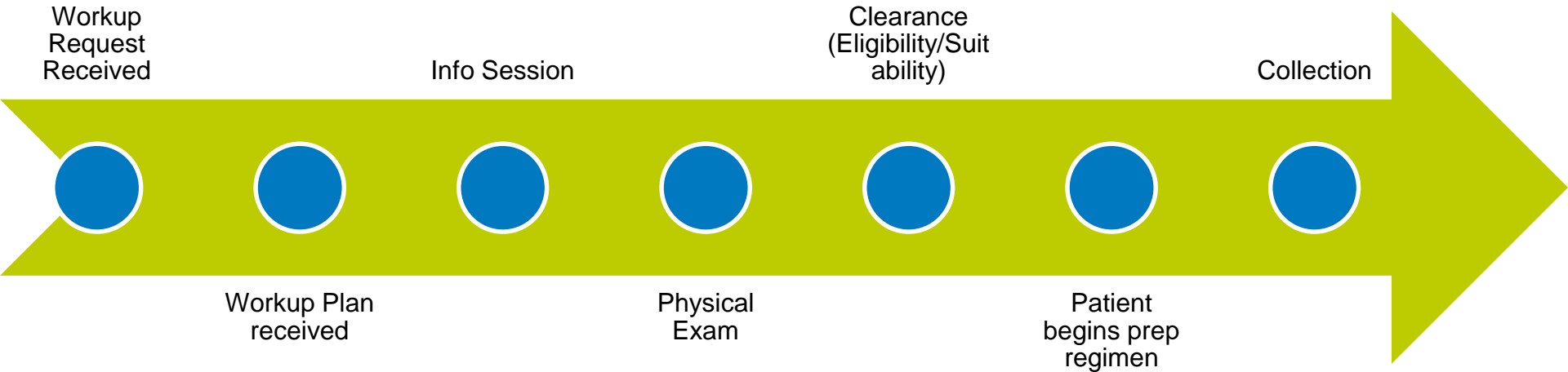
Date Comments:

Workup Plan Received

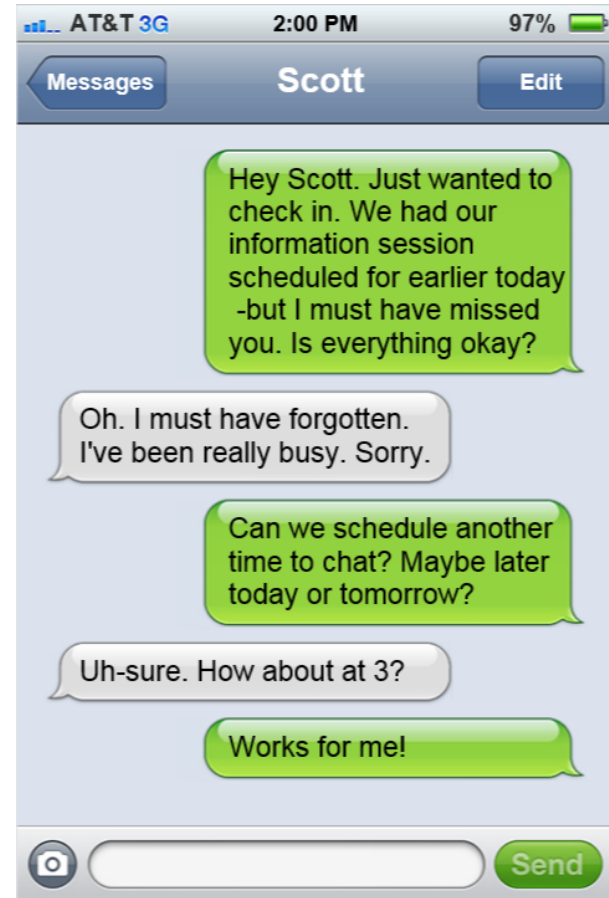
Patient Update



Path of a Product



Info Session



What Would You Do?



Try to contact him again via text, call, email.

Inform Case Manager right away.

If no response have a colleague reach out to him? With a different number?



Challenges

- Donor not responsive.
- Possible impact to PE date.
- Is the donor *really committed?*



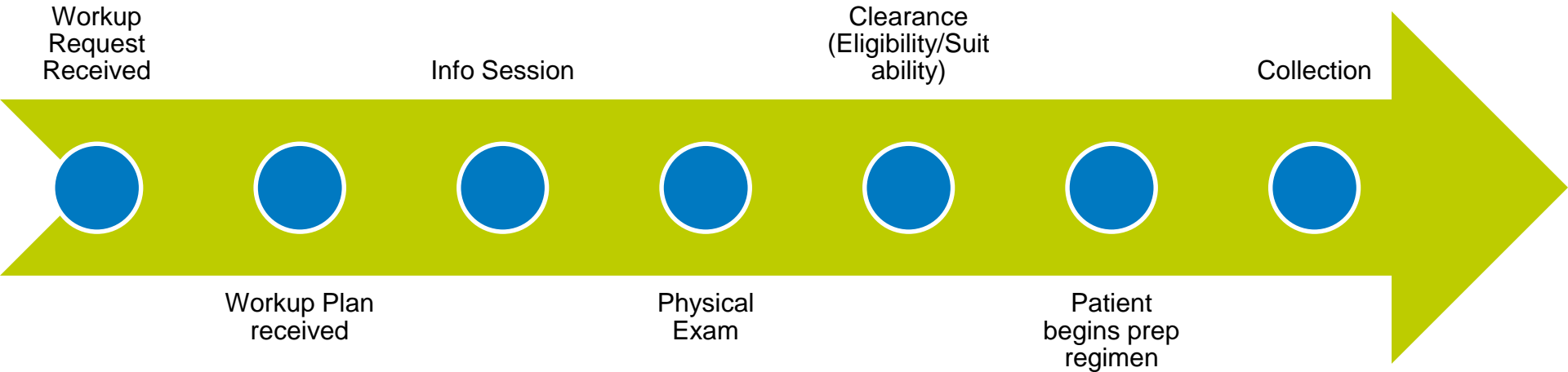
Resources

- Another colleague w/ a different number.
- Donor's contacts in their file.
- Be tenacious and call in the evening

2nd Scheduled Info Session



Path of a Product



TC asks for itinerary before confirming prep



Physical Exam



What Would You Do?



Just repeat testing, inform CM later & cross your fingers nothing happens.

Inform CM about lab testing & obtain approval for the extended medical. Discuss possible suitability issue.

PE Problems...





Challenges

- Marrow only now needs info session for marrow
- Capacity issue w/ CC
- Auto units



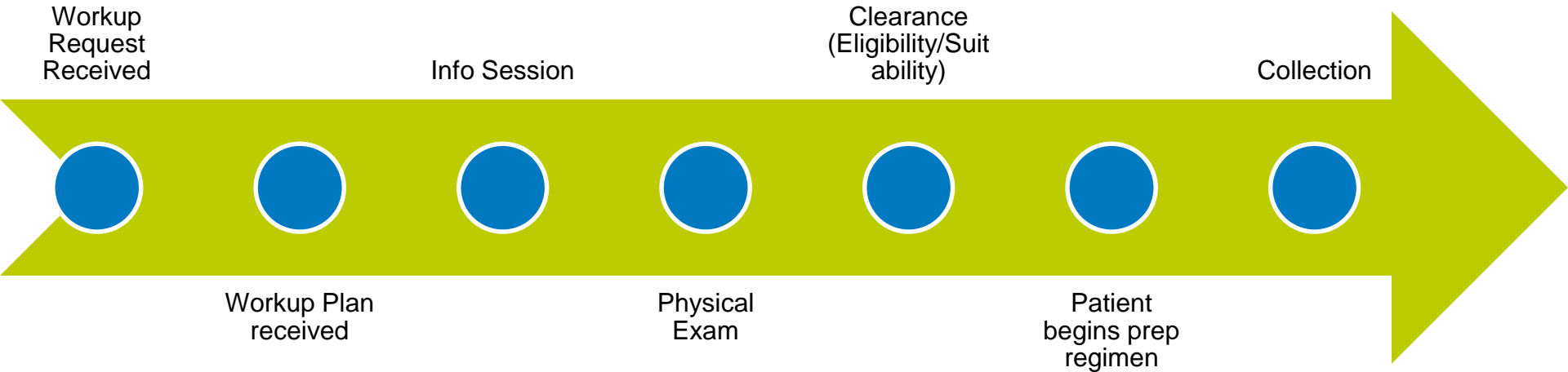
Resources

- AC/CC liaison

TC Communication



Path of a Product



National Marrow Donor Program®
NOTIFICATION OF DONOR CLEARANCE

Recipient Identification Number: _____
NMDP Donor or Cooperative Registry ID: _____

The above donor is **suitable and willing** to donate the following product (*check one*):

☐ HPC, Marrow ☐ HPC, Apheresis ☐ MNC, Apheresis

Collection information:

☐ All parties agree to the collection date(s): _____
Patient prep date: _____ ☐ N/A
Filgrastim start date: _____ ☐ N/A
☐ The DC/TC propose a tentative collection date(s): _____
☐ Collection dates pending

Verification:

☐ Attached, please add final signature and return as soon as possible
☐ Pending
☐ Sent previously on: _____

Transport information:

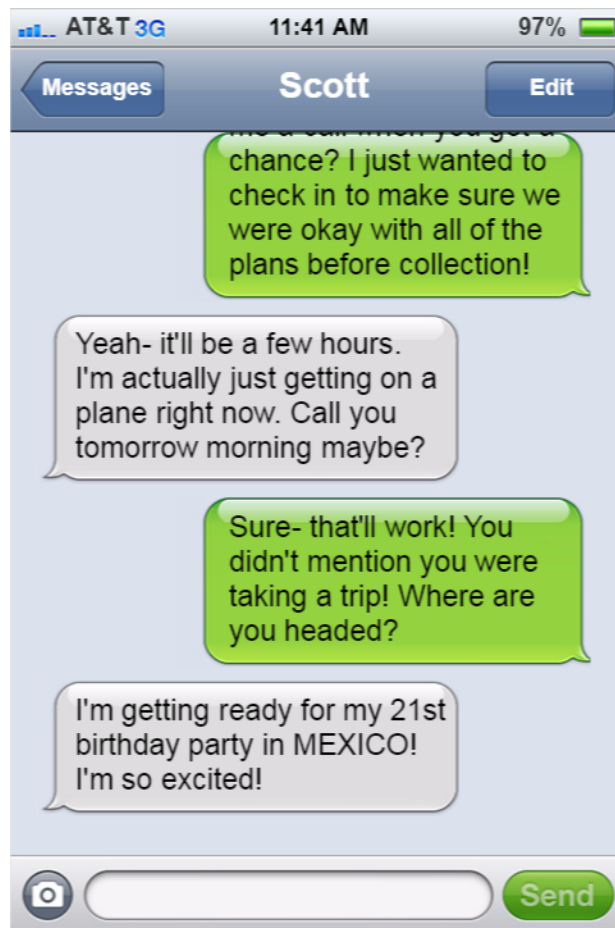
☐ Hand carried by: ☐ DC ☐ TC ☐ Other: _____
☐ Shipped by commercial company
☐ Undecided at this time

Note to TC:

Note to DC:

Completed By: _____ Date (MM/DD/YY): _____

Suitability & Eligibility Received



What Would You Do?



☐ Do nothing until Scott returns.

☐ Inform the Case Manager about impending travel.

☐ Tell Scott not to go...

Eligibility Changed!

- Zika Assessment
- Declaration of Eligibility
- DEHR (Donor Eligibility History Report)
- SUMN (Statement of Urgent Medical Need)
- Appropriate Attachments (A2, B, C, D)
- Amend the HHSQ to add a Malaria risk



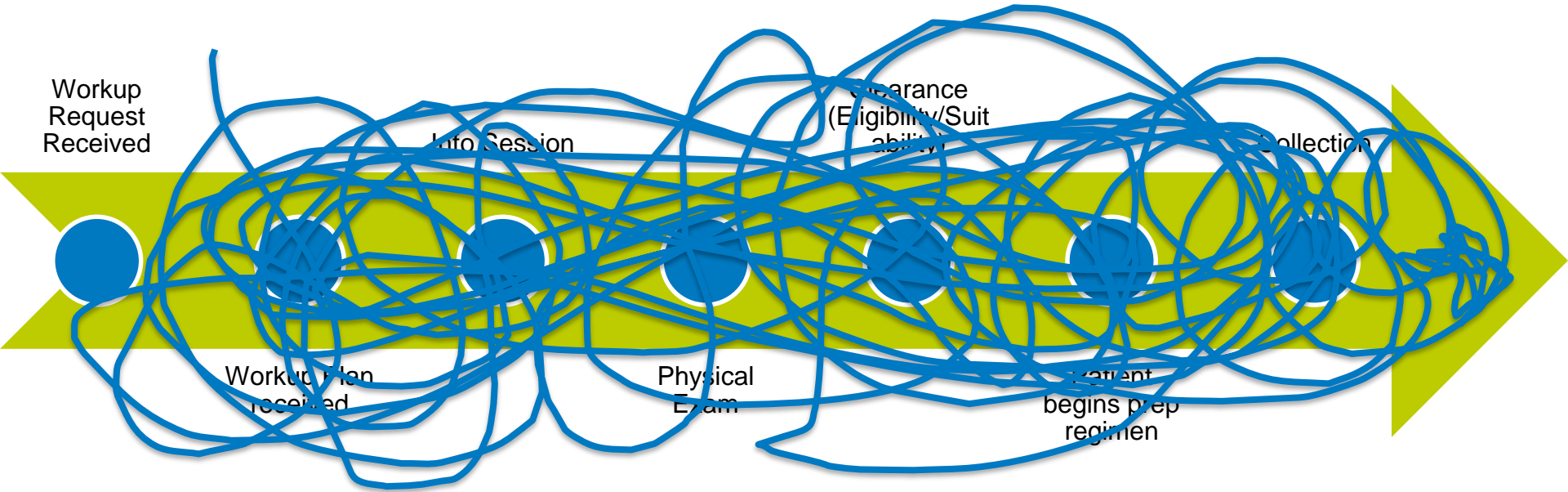
Accept?



Finally...



Path of a Product



What Will You Do?



Evaluation Reminder

Please complete the Council Meeting 2017 evaluation in order to receive continuing education credits and to provide suggestions for future topics.

We appreciate your feedback!

What Will You Do?



Pick up the phone.



Share w/ a colleague back at the office.



Remember- there's always two sides to the story...



All of the above!