ABO Determination

Membership and Professional Standards Committee
February 26-27, 2019
[redacted]
Compliance Operations Analyst

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Overview

- Two cases in this cycle regarding ABO determination in donors who received massive transfusions
- One case went through the standard PCSC review process
- Other case went through MPSC Leadership pathway that led to an informal discussion
- Review for similarities and differences, determine an action for each case
- Results of preliminary UNOS data search

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Relevant Policy

- **2.6.A Deceased Donor Blood Type Determination and Reporting**

  The host OPO must ensure that each deceased donor's blood type is determined by testing at least two donor blood samples prior to the match run. The host OPO must develop and comply with a written protocol to resolve conflicting primary blood type results.

  Deceased donor blood samples must:

  1. Be drawn on two separate occasions
  2. Have different collection times
  3. Be submitted as separate samples
  4. Have results indicating the same blood type

  The host OPO must document that blood type determination was conducted according to the OPO's protocol and the above requirements.

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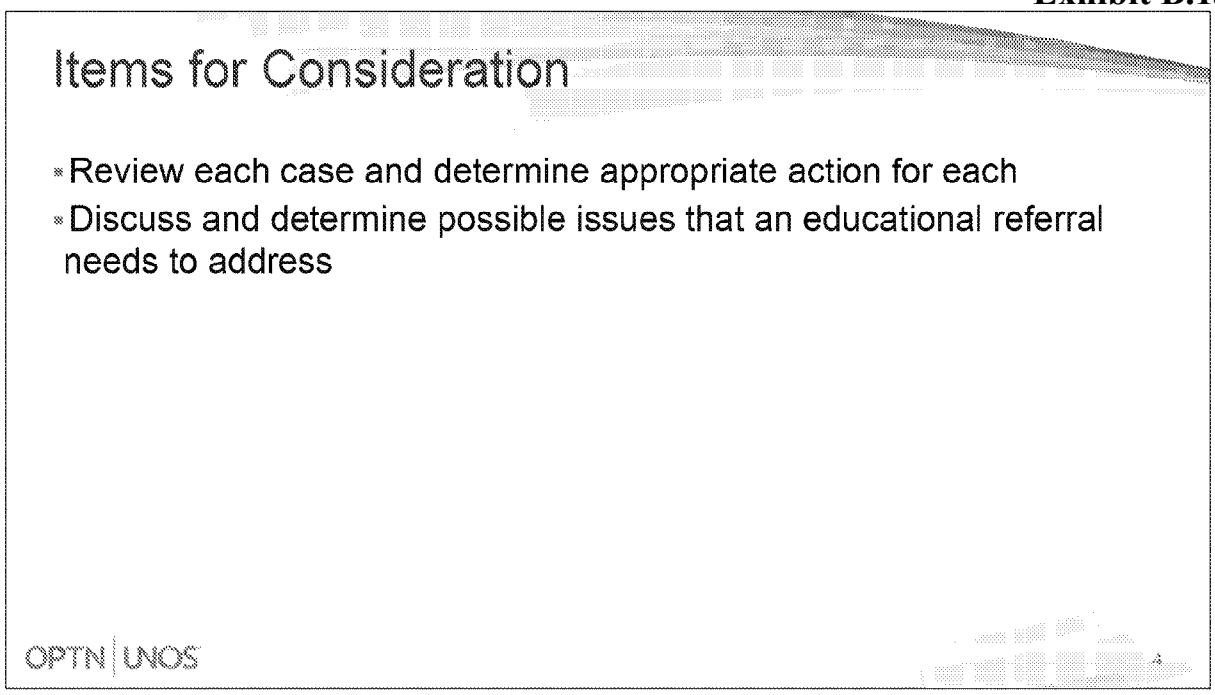
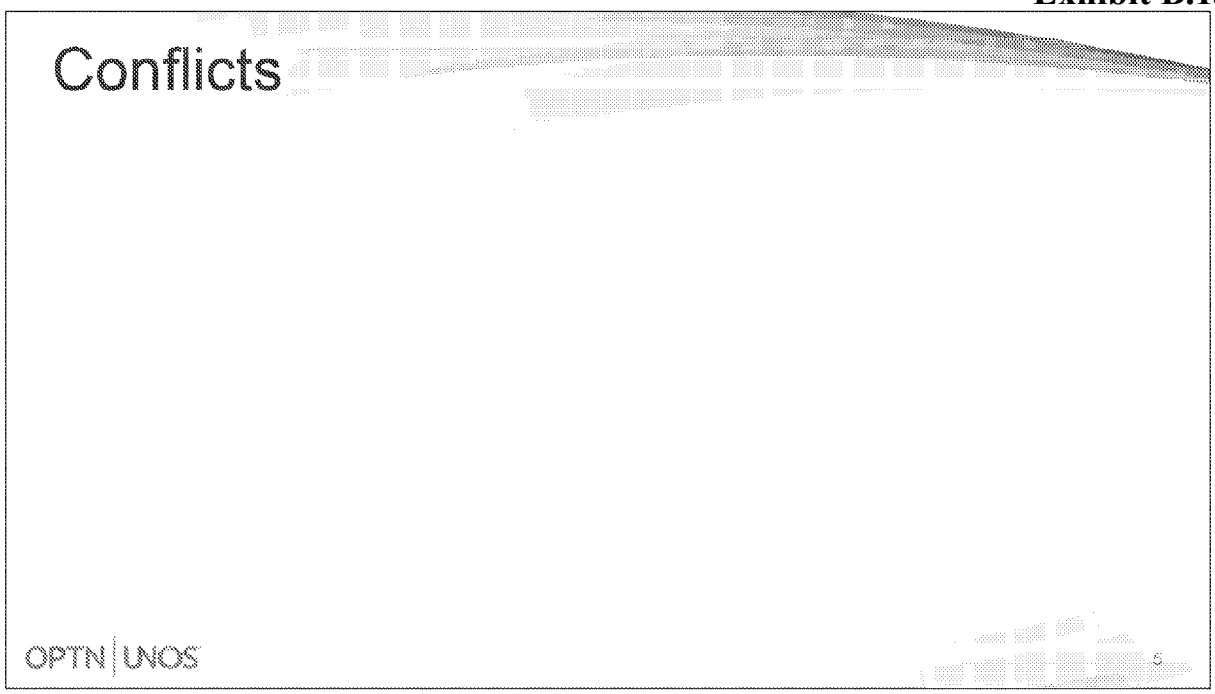


Actions can be different if the situation or member response is different, but otherwise the MPSC should be as consistent as possible .


Conflicts
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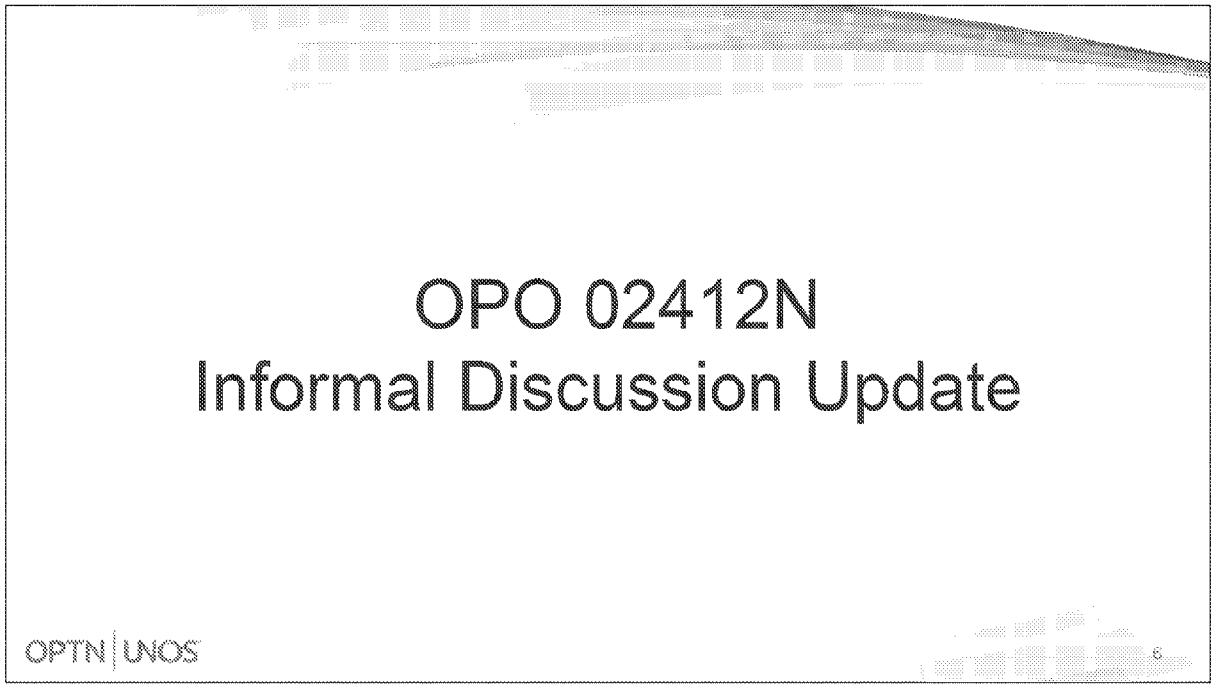
OPO 02412N
Informal Discussion Update
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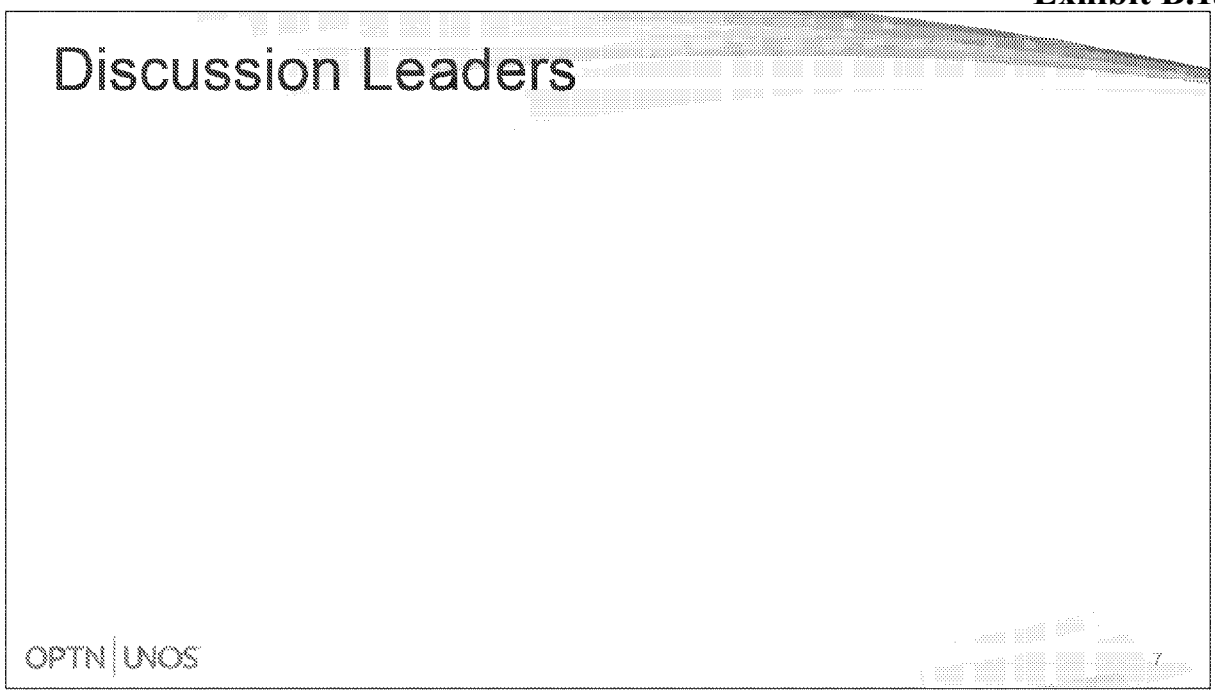
6


Discussion Leaders
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Case Overview

- In late November, OPO reported an incorrect ABO typing that resulted in incompatible organ transplants leading to two organ discards and one recipient death. MPSC held an informal discussion to discuss the member's root cause analysis and corrective actions regarding this event.
- 24 y/o female, motor cycle vs. tree with head trauma. The donor was 5' 6" tall and weighed 130 pounds, resulting in an estimated total plasma volume of 2356 ml and an estimated total blood volume of 3926 ml.
- Massive transfusions of 12 units of PRBC, 10 units of FFP, and 3 units of platelets resulted in administration of 3700 ml of plasma products and 3000 ml of blood products.
- Pre-transfusion blood drawn at admission was hemolyzed and unable to be used for ABO typing.

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ABO typing

Sample	Location	Result	Reported
Admission	Donor Hospital	Indeterminate	Hemolyzed
ABO #1	Donor Hospital	ABO O Fwd O, Rev A	O
ABO #2	Serology Lab	Indeterminate Fwd O, Rev A	Indeterminate
ABO #3	Donor Hospital	ABO O Fwd O, Rev O	O
OR Sample	OPO's Local Hospital	ABO A Fwd A, Rev A	A

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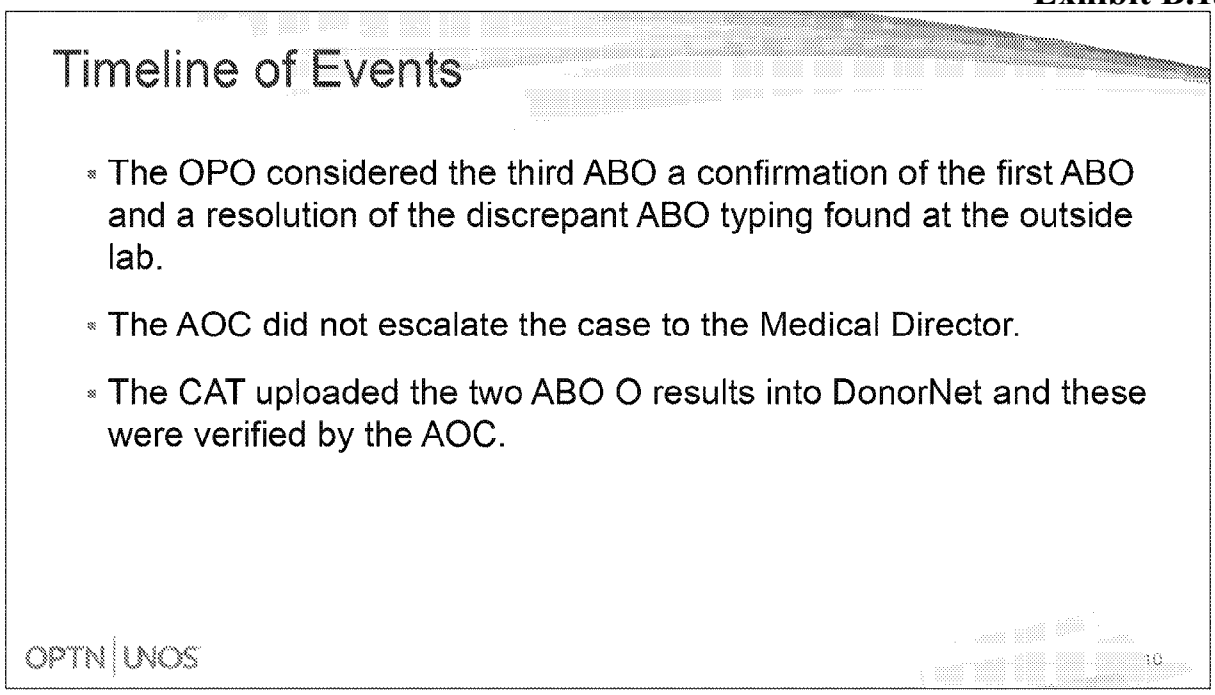
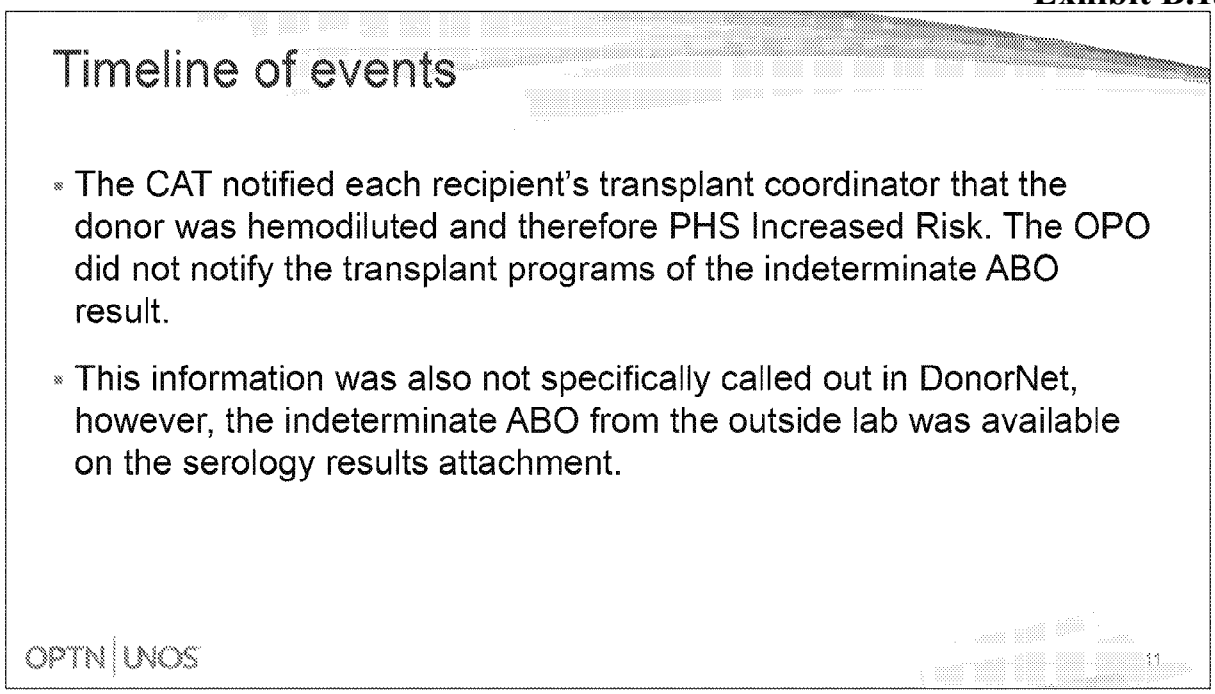


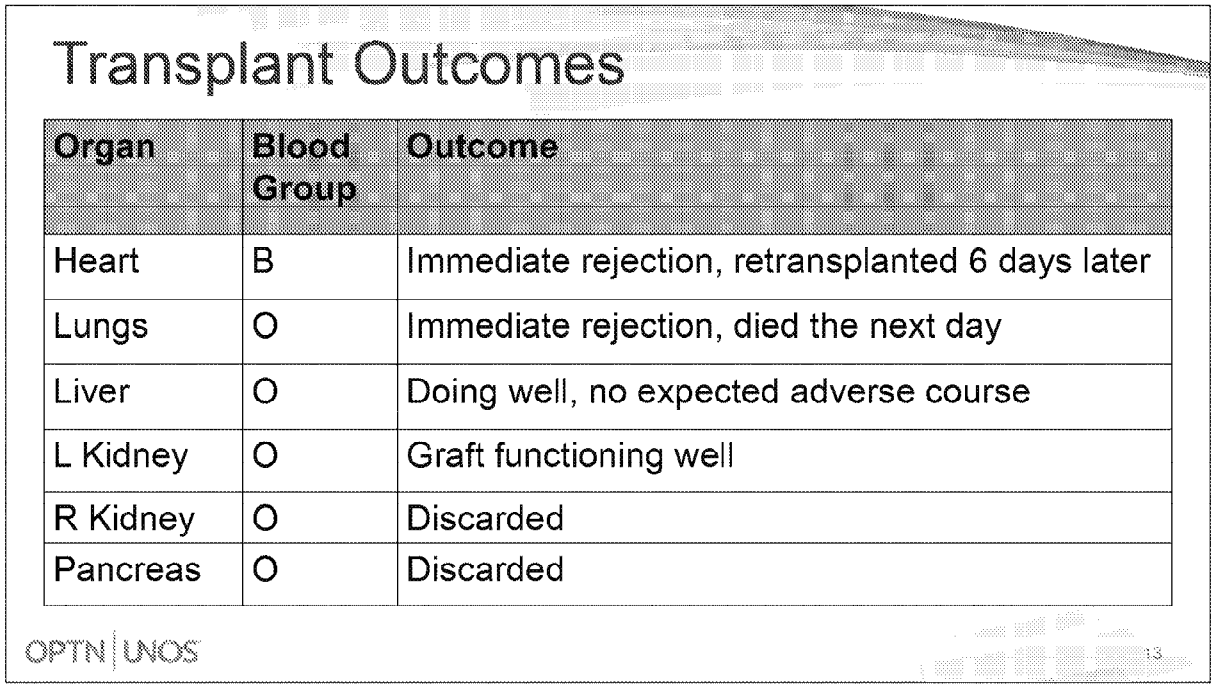
CAT- Clinical Allocation Technician



CAT – Clinical Allocation Technician

Timeline of events

- The day after procurement, the pancreas program contacted the OPO to alert them that the blood sent with the pancreas resulted in ABO A.
- The OPO then alerted the other receiving centers, but the heart, lungs, liver, and left kidney had already been transplanted.
- All receiving centers and the OPO reported this event through the OPTN Improving Patient Safety Portal.



Hospital 41473N received the heart and transplanted it into an ABO B recipient. After release of crossclamp, the heart stiffened and became edematous. Hospital 41473N was unable to get the recipient off of CPB, and converted to VA ECMO. After six days the heart recipient was retransplanted.

The heart recipient is doing well and was discharged home 22 days after the second transplant.

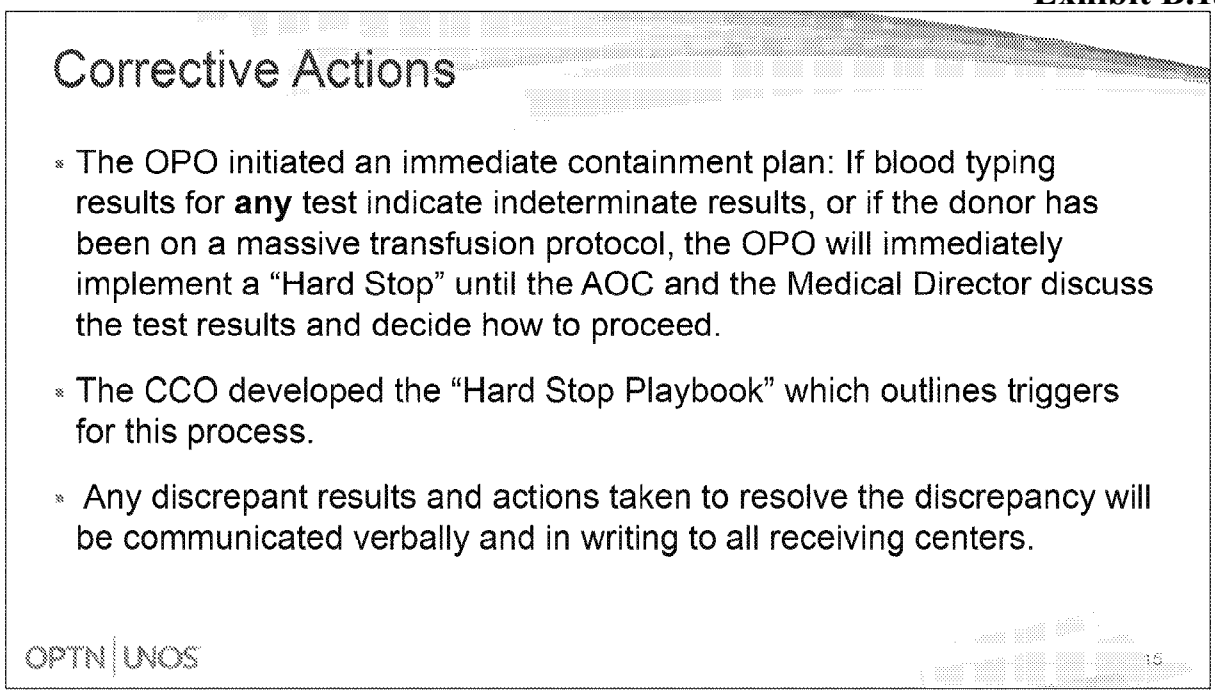
Hospital 46029N received the liver and transplanted it into an ABO O recipient. The recipient is doing well and is not expected to have an adverse course related to the incompatible ABO.

Hospital 35577N received the pancreas for an ABO O recipient. Using blood taken during procurement, Hospital 35577N re-ran donor ABO and found a mix of A and O blood types. Hospital 35577N called OPO 02412N and was informed of the massive transfusion the donor received, and that OPO 02412N had one indeterminate blood typing result. Hospital 35577N aborted the procedure and did not transplant the intended recipient. The pancreas was later discarded.

Hospital 03283N received the lungs, the left kidney, and the right kidney. The left kidney was transplanted into an ABO O recipient. The graft is functioning well and Hospital 03283N believes that the ABO incompatibility will not affect graft function. The right kidney was discarded after the ABO discrepancy was found.
The lungs were transplanted into an ABO O recipient who showed immediate signs of rejection and was put on ECMO. The lung patient died the next day.

Root Cause Analysis

- At the time of the event, the OPO did not have a clear process to address an indeterminate result besides drawing another sample or checking for an available sample.
- At the time of the event, the OPO did not have a clear process for when an indeterminate result should be escalated to the Medical Director.
- The OPO also noted that staff did not adequately recognize and respond to the "Indeterminate" result from the outside laboratory.



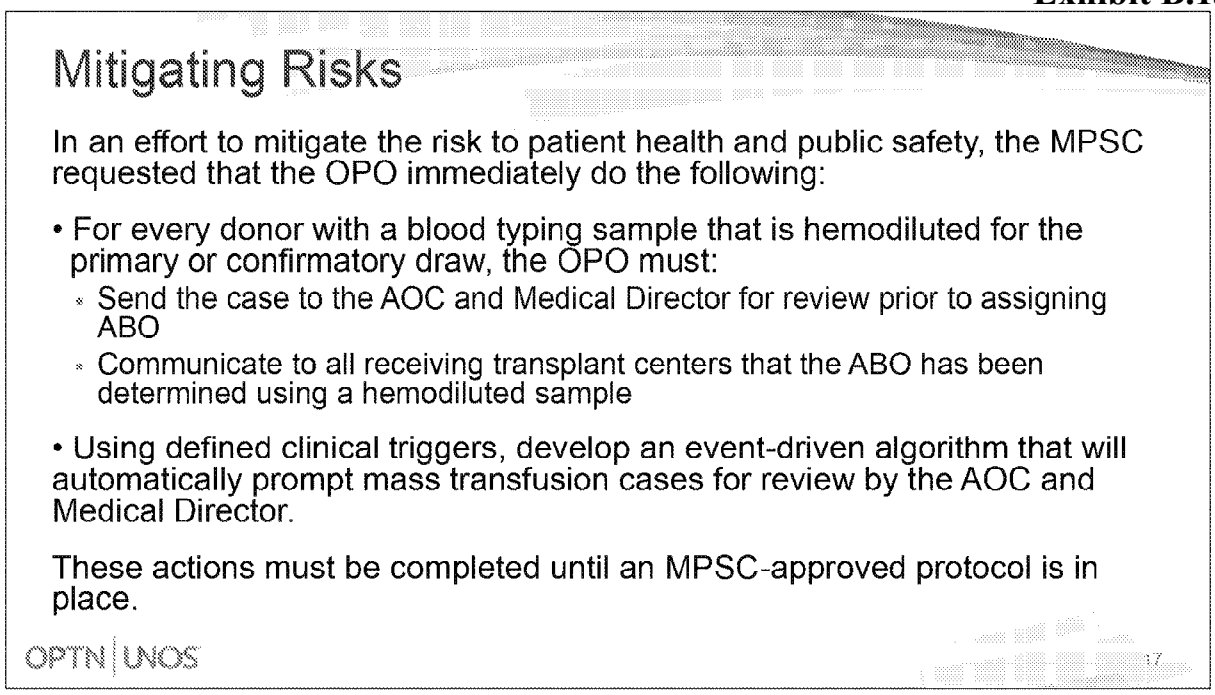
CCO: Chief Clinical Officer

Monitoring plans: OPO 02412N will monitor 100% of cases of indeterminate results and massive transfusion protocol for documentation of discussion between the AOC and Medical Director.

Leadership Call

- January 17th - MPSC Leadership reviewed the OPO's containment plan and response to the event. Leadership was concerned by:
  - Failure of OPO's staff and AOC to recognize the potential safety consequences of indeterminate blood typing issues
  - Use of broad terminology such as mass transfusion and indeterminate blood type instead of firm clinical and situational triggers when determining which donor cases go for AOC and Medical Director review
  - OPO did not accept responsibility for this event and look internally to assess what OPO staff could have done to prevent this event, regardless of the actions of the donor hospital

Offered the member an informal discussion to gather more information

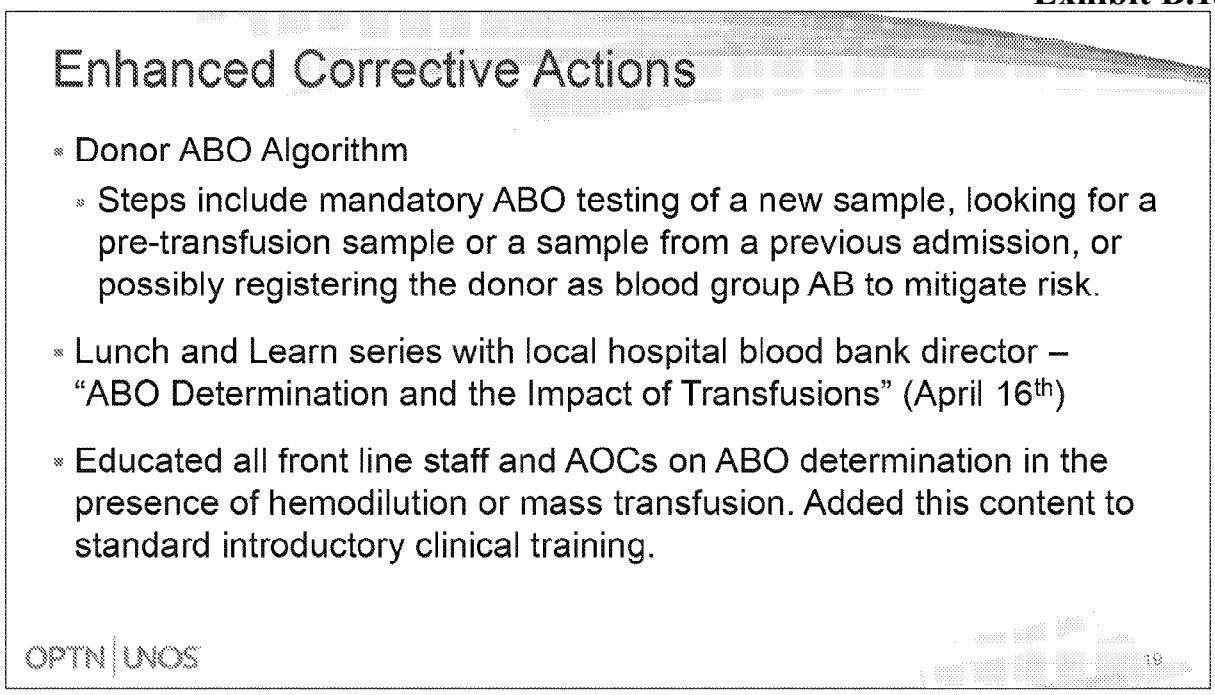


The MPSC has also requested that the OPO submit the following documentation:
• An updated RCA that includes a comprehensive internal assessment of actions the OPO could have taken to prevent this type of event.
• An updated corrective action plan that includes policy development and staff and leadership training regarding mass transfusions and ABO typing.

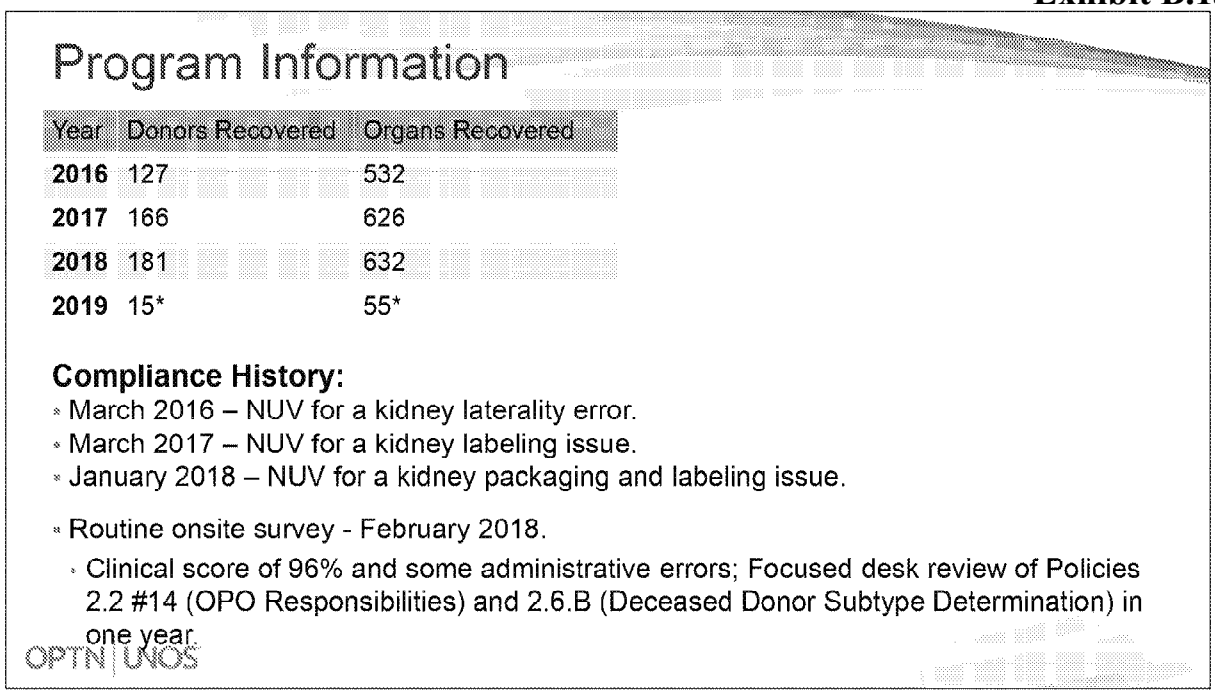
Also requested but not listed in the letter:
An description of the role and scope of responsibilities of the Medical Director at the OPO.

Informal Discussion

- January 28, 2019
- Presented a more robust RCA and CAP, identifying several internal actions that could be implemented to mitigate the risk of recurrence.
- Discussed their search for guidance material on ABO determination in the presence of hemodilution and massive transfusions.



The donor ABO algorithm is a process map for identifying & resolving ABO determination in hemodilution and massive transfusion protocols.

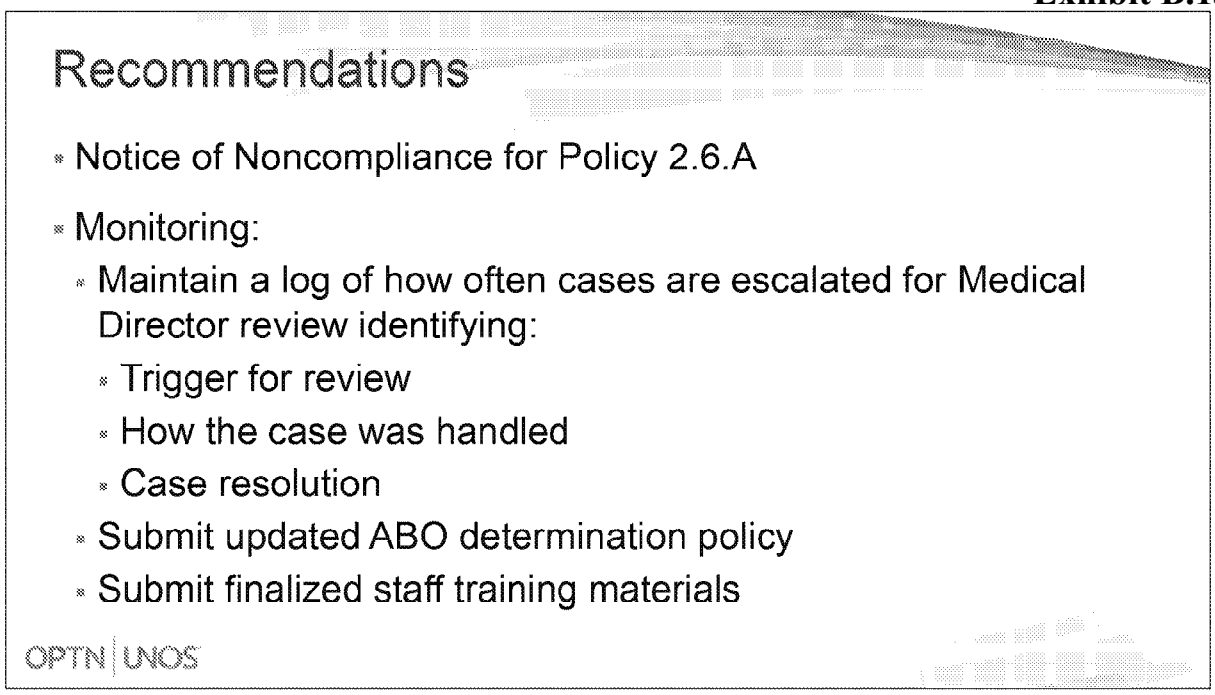


Data through 1/31/19.
For Policy 2.6.B, two donor records had ABO subtypes listed as A2, both source documents report subtype A1. All organs from both donors went into blood group A recipients.

For Policy 2.2 #14, one donor record was missing ABO, subtype, and infectious disease source documentation in DonorNet.

RCA (subtyping): OPO changed serology labs in late 2016 and failed to train staff on new ABO reporting format. Staff confused subtype reporting with Rh factor. Containment plan: Quality Dept. will audit every donor's ABO subtyping entry into DonorNet prior to the donor leaving for the OR for the next 30 days or the completion of the RCA and CAP.

Scheduled desk audit of 2.2.14 and 2.6.B is in September 2019.



Workgroup date – January 22

2.6.A Deceased Donor Blood Type Determination and Reporting

CAP Updates – 2/22/19

- Requiring that all blood samples for ABO testing be evaluated for hemodilution and qualified using the process for serology testing. A quality check of the process and results were submitted. (Att. 1)
- Completed a second, more formal case review of the event. (Att. 2)
- Finalized the ABO Determination and Results process maps. (Att. 3)
- Updated standard clinical training to include ABO Determination – Forward and Reverse Typing, discussing the impact of transfusions and hemodilution. Discussing this may be a "stand-alone" training for staff. PowerPoint submitted. (Att. 4)

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CAP Updates – 2/22/19

- Updated policies (Att. 5)
- Monthly review of the Hard Stop process to ensure adherence to process, results of the first quality review were submitted. (Att. 6)

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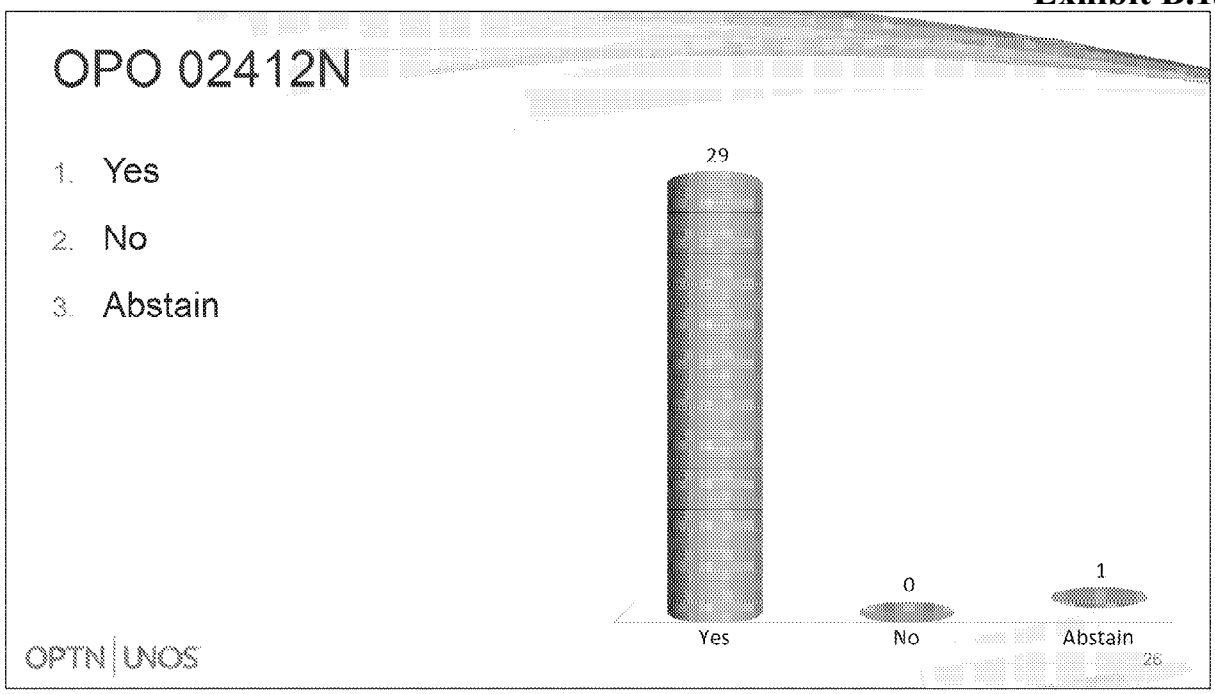
Items for Consideration

Does the MPSC approve the subcommittee's recommendations?

MPSC Resolution

- Notice of Noncompliance for Policy 2.6.A
- Monitoring:
  - Maintain a log of how often cases are escalated for Medical Director review identifying:
    - Trigger for review
    - How the case was handled
    - Case resolution
    - Include in letter: in cases of unexpected graft failure, may consider looking at that case to see if it didn't meet these criteria but still had ABO issues


OPO 02412N
1. Yes
2. No
3. Abstain
29
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1
Yes
No
Abstain
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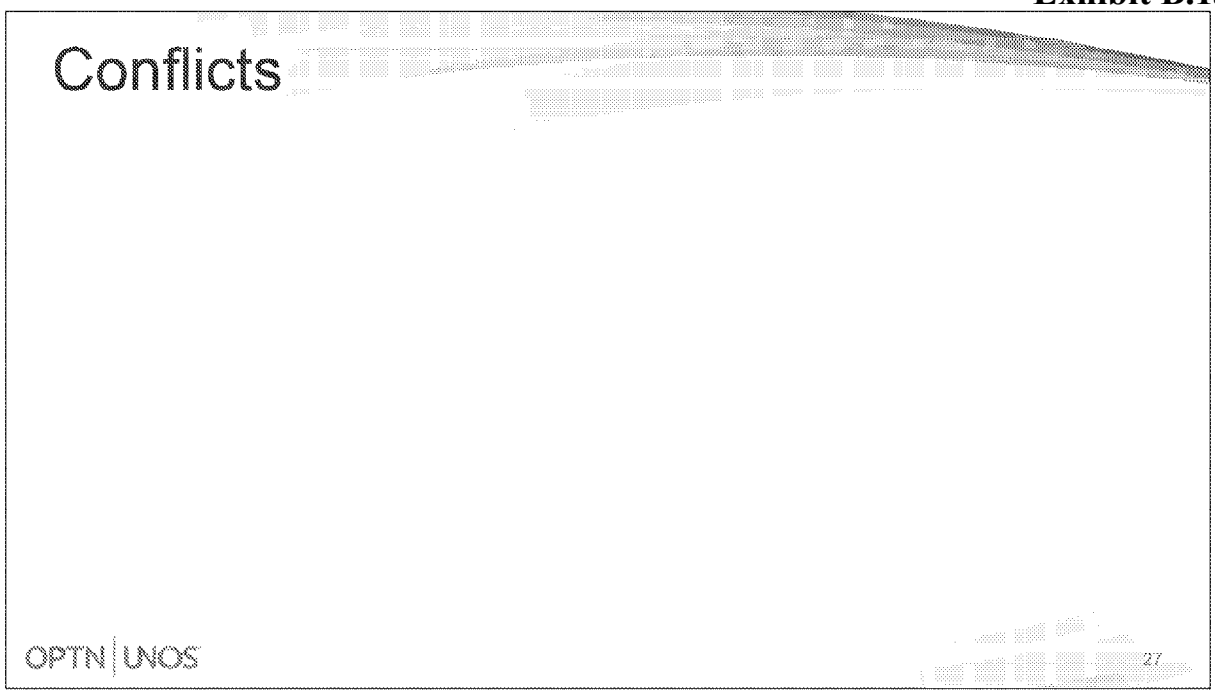
Conflicts
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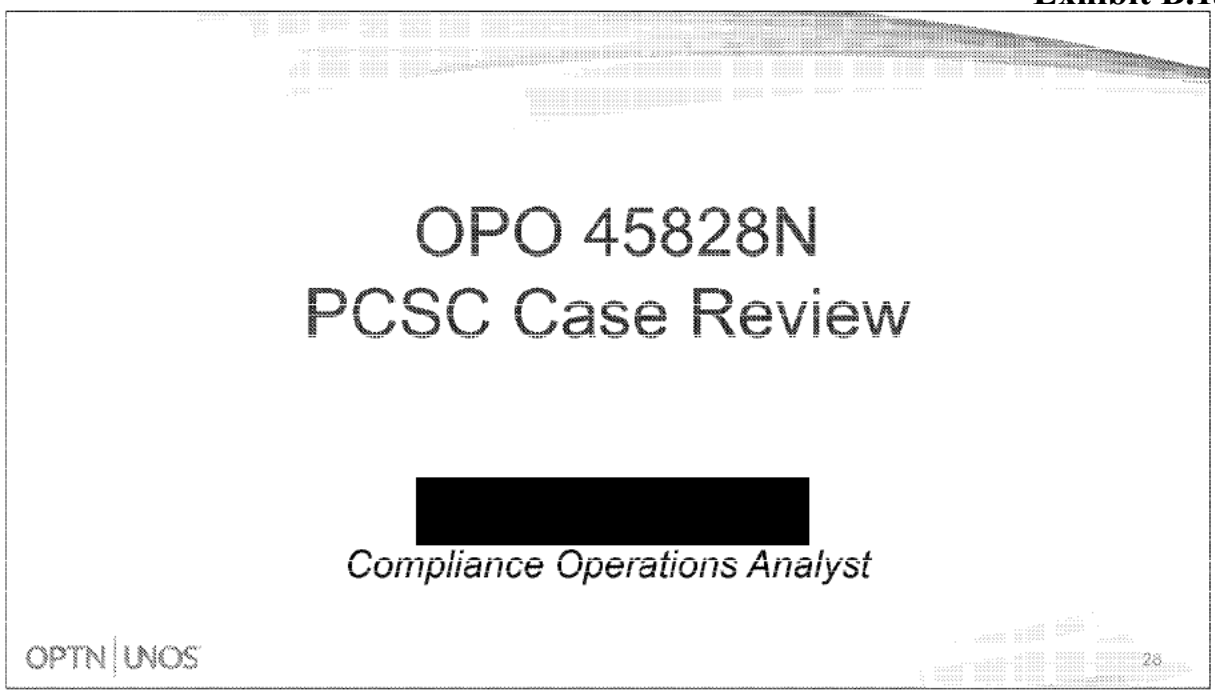
OPO 45828N
PCSC Case Review
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Compliance Operations Analyst
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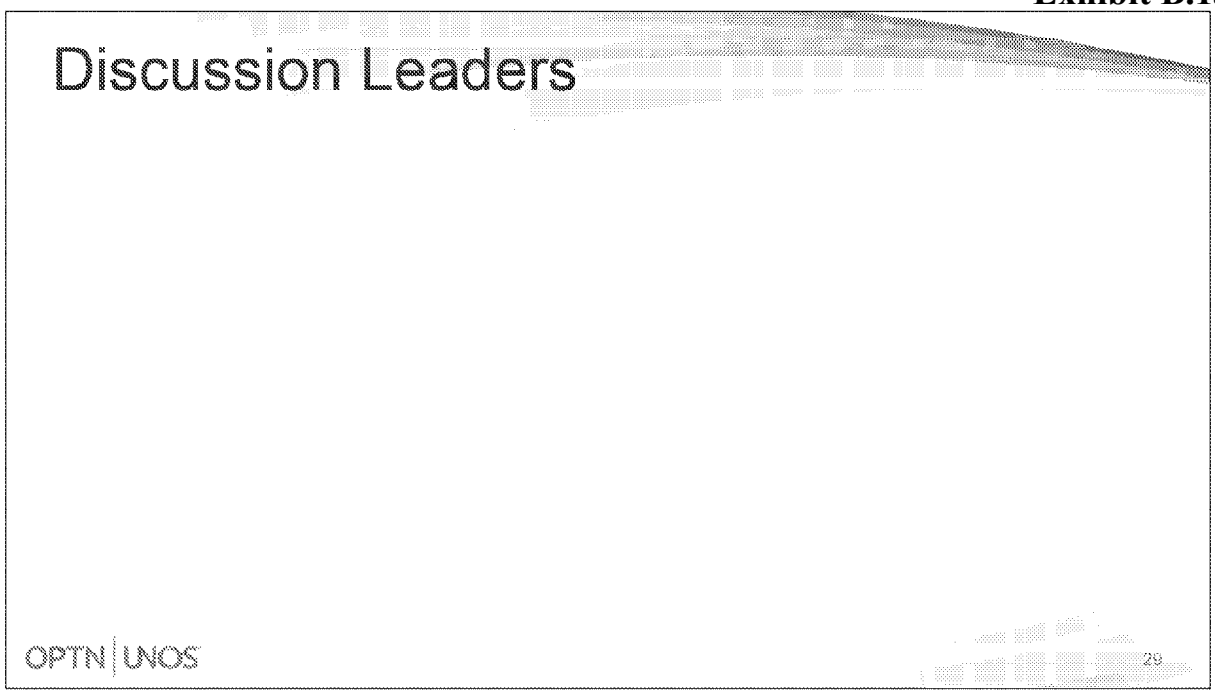
Discussion Leaders
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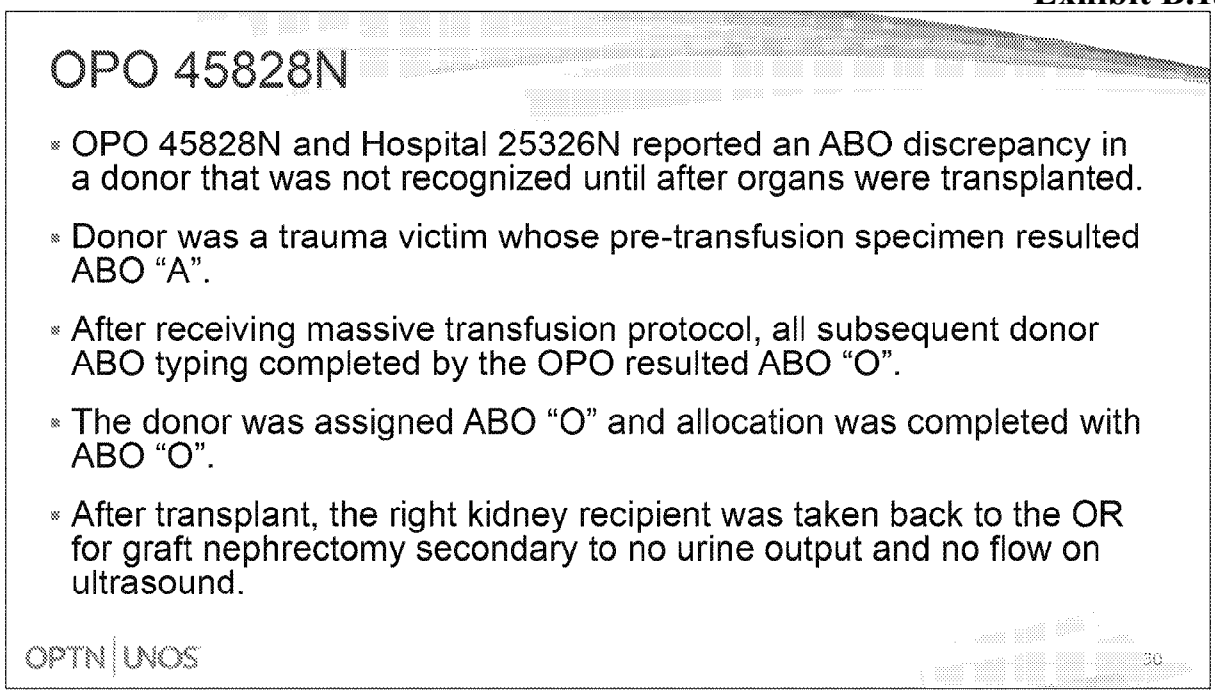

2.6 Deceased Donor Blood Type Determination and Reporting: "Host OPOs must develop and comply with a written protocol for blood type determination and reporting..."

OPO 45828N

- Liver transplant surgeon immediately notified. Liver recipient underwent plasmapheresis and continues to not show any signs of rejection.
- Left kidney in transit when the accepting center received notification of the potential ABO incompatibility issue. Center reviewed the details and elected to transplant the kidney into the intended recipient, as that patient was ABO "A."
- No other organs from this donor were allocated.

Corrective Actions

- Local transplant hospital blood bank Medical Director provided training on ABO typing processes, including ABO discrepancies, for OPO staff.
- Training was recorded for use in new employee training.
- OPO updated policy and procedures to include more specific guidance about what to do in the presence of discrepant results, most notably, to use the most restrictive ABO if the discrepancy is not resolved.
- Current clinical coordinators trained on ABO, HLA, and Archive Serum verification.
- ABO training for new employees will be updated to include the necessary steps to resolve primary blood base type discrepancies.

Volumes and History

Year	Donors	Organs Recovered
2016	70	244
2017	68	263
2018	68	226
2019	4*	19*

*As of February 14, 2019

MPSC history:

- 10/2016: NUV for rescinded liver offer and an expedited recovery where the OPO did not acquire all tissue-typing material or make mandatory share offers within the required time period.
- 6/2016: Board of Directors released OPO from Probation. (OPO placed on Probation in November 2014 for site survey issues, self-reported violations, and the results of a peer visit.)

Survey: Unannounced on-site survey as part of OPO's Probation monitoring. Clinical score 99%, few admin errors. MPSC 2/2016 closed with no action.

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Reviewer Comments

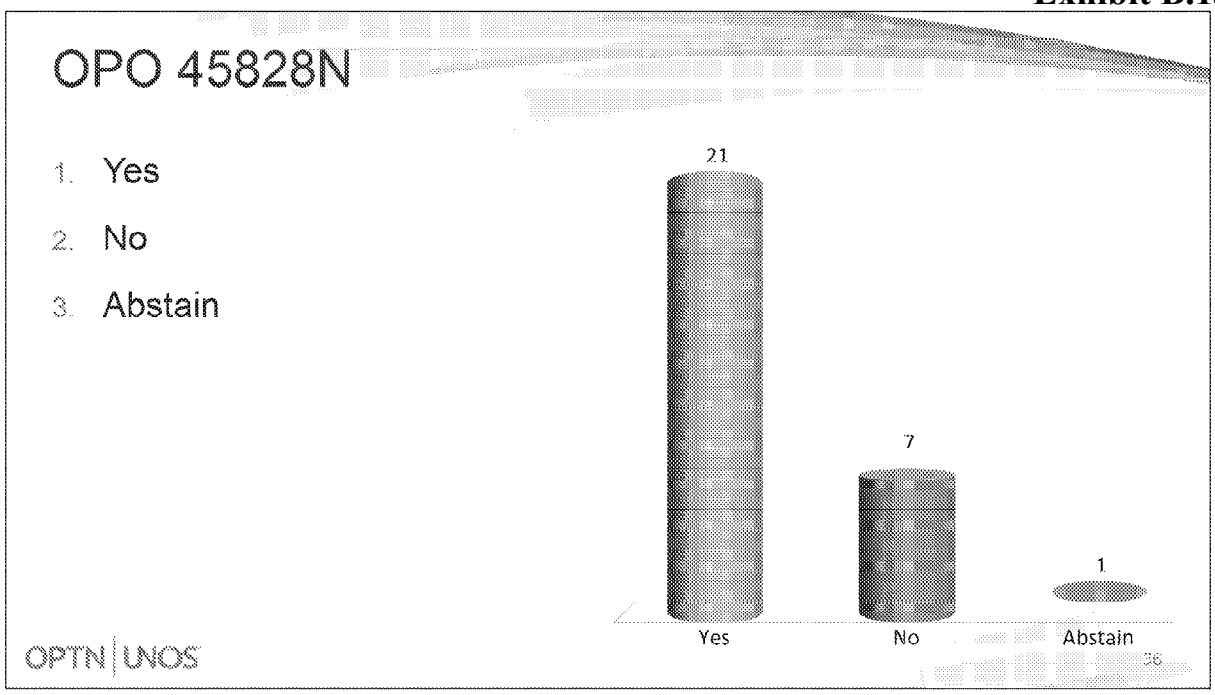
Reviewer 1: I can agree to the Notice of Non-compliance with OPTN 2.6, but due to the nature of these case (including the loss of a kidney), I would recommend we look at this closer at this case and consider a review of Policy 2.6 to actually be more prescriptive in how these types of donors should be listed in DonorNet.

Reviewer 2: This major event should be discussed at the meeting as it has implications for safety across the system. I was not aware of the potential for mistyping to occur under these circumstances although in reading about "mixed field" it seems this is a real possibility in trauma cases where extensive blood is needed immediately (and therefore O is used). Frankly it is surprising this hasn't occurred before (or has it?) It may be there should be some additional policy development related to donors who type as O in these circumstances -major trauma, significant type O blood units, hemodiluted sample, prior discordant result.

Reviewer 3: Agree with other reviewers that additional guidance should be provided on how to address these types of trauma patients for patient safety reasons and prevention of loss of transplantable organs. I do believe a notice of non-compliance is applicable, but would like to see the updates and guidance they have since provided to their staff. That was not provided with their submission.

Resolution

- Notice of Noncompliance for Policy 2.6.A
  - Submit monitoring of process and adherence to CAP


OPO 45828N
1. Yes
2. No
3. Abstain
21
7
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Yes
No
Abstain
OPTN | UNOS

Relevant Policy

- **2.6.A Deceased Donor Blood Type Determination and Reporting**

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Case Comparison

	45828N	02412N
Event report date	• 9/28/2018	• 11/28/2018
Who reported?	• Donor OPO • Right Kidney Transplant Center	• Heart Transplant Center • Liver Transplant Center • Pancreas Transplant Center
Containment plan at time of reporting?	• Not applicable	• Yes - spoke with OPO day event reported and they had created a containment plan
Donor transfusion status	• Massive transfusion protocol. OPO reports 21 units within first 10 hours of admission.	• Massive transfusion protocol. OPO reports 26 units during attempt at life-saving surgery.

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HRSA Notification? 045828N - NO, 02412N - YES

Case Comparison - Outcomes

	45828N	02412N
Left kidney	• Transplanted into ABO A recipient • Graft functioning	• Transplanted into ABO O recipient • Graft functioning
Right kidney	• Transplanted into ABO O recipient • Hyperacute rejection • Patient explanted and alive	• Discarded after ABO error found
Liver	• Transplanted into ABO O recipient • Patient plasmapheresed • No signs of rejection and alive	• Transplanted into an ABO O recipient • Graft functioning

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Case Comparison - Outcomes

	45828N	02412N
Lungs	• Not recovered	• Transplanted into ABO O recipient • Hyperacute rejection • Recipient died the next day
Heart	• Not recovered	• Transplanted into ABO B recipient • Hyperacute rejection • Explanted, re-transplanted six days later with graft functioning
Pancreas	• Not recovered	• Allocated to an ABO O recipient • Receiving center found ABO error while performing confirmatory typing • Discarded

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Case Comparison - ABO

Donor ABO	45828N	02412N
Typing #1	• 9/23/18, pre-transfusion • ABO: A • Listed on transfusion record, not posted or removed from donor attachments	• 11/24/18, post-transfusion • ABO: O • ABO: Forward O, Reverse A • Reverse typing not communicated to OPO
Typing #2	• 9/27/18, post-transfusion • ABO: O	• 11/25/18, post-transfusion • ABO: Indeterminate • ABO: Forward O, Reverse A • OPO aware of discrepancy
Typing #3	• 9/25/18, post-transfusion • ABO: O • Forward O, Reverse A	• 11/25/18, post-transfusion • ABO: O • ABO: Forward O, Reverse O
Typing #4	• 9/27/18, post-transfusion • ABO: O	• Not applicable

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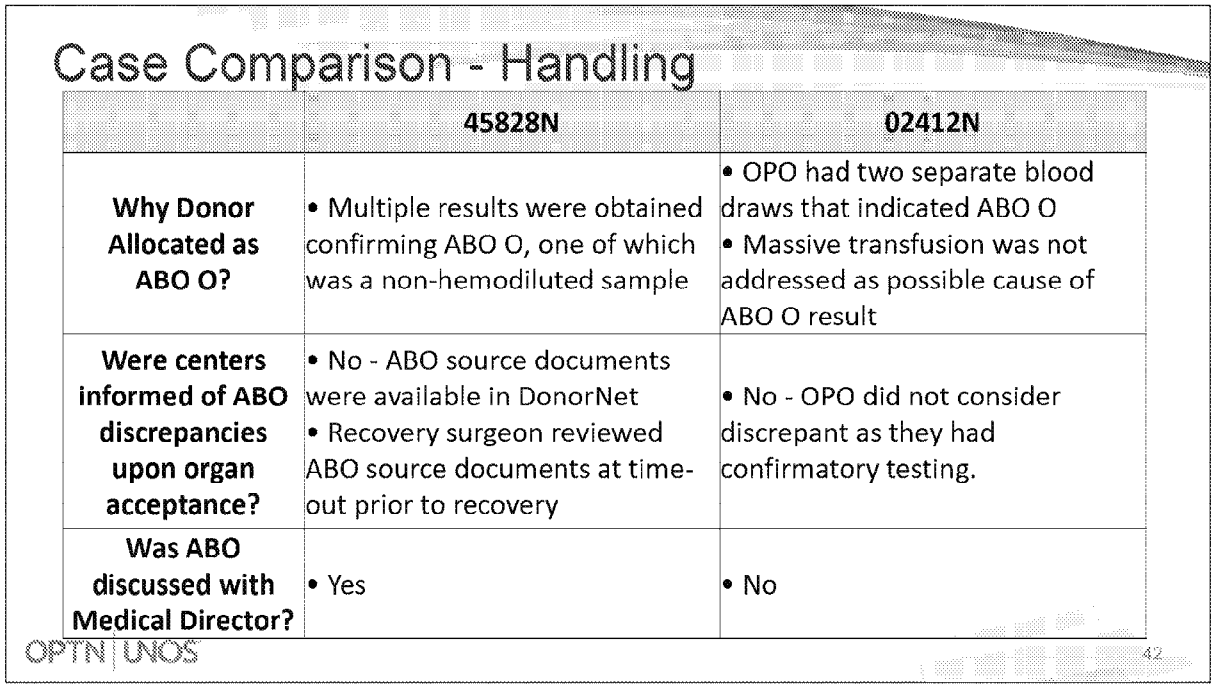

Case Comparison - Handling

	45828N	02412N
Why Donor Allocated as ABO O?	• Multiple results were obtained confirming ABO O, one of which was a non-hemodiluted sample	• OPO had two separate blood draws that indicated ABO O • Massive transfusion was not addressed as possible cause of ABO O result
Were centers informed of ABO discrepancies upon organ acceptance?	• No - ABO source documents were available in DonorNet • Recovery surgeon reviewed ABO source documents at time-out prior to recovery	• No - OPO did not consider discrepant as they had confirmatory testing.
Was ABO discussed with Medical Director?	• Yes	• No

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Case Comparison – CAP

	45828N	02412N
CAP	• New policy - guidelines about how to address discrepant typing: pre-transfusion specimen for addtl testing, historical blood type with source docs, or sending addtl specimen to independent lab. When both discrepant samples are pre-transfusion, 2 new pre-transfusion samples will be tested at 2 different labs. • ABO Huddle prior to listing. Participants: Med Director, AOC, on-site clinical coordinator, SME. • Last resort, will assign the more restrictive blood type, based on pre-transfusion sample. • Training presented to staff by transplant Blood Bank Med Director. This training will be used in new employee training.	• If **any** ABO results are indeterminate, if the donor had massive transfusion, or if any ABO blood sample is hemodiluted, case is placed on hold for AOC and Med Director resolution. Done by finding a pre-transfusion sample, a historic sample, rerun ABO samples at an independent lab, or assigning the most restrictive blood group. • Indeterminate ABO: Med Director will contact the blood bank or lab director/manager to discuss the results. • Hard Stop Playbook was developed and reviewed with staff. • Cases will be audited for compliance to new policies and procedures. • OPO will communicate to all receiving centers any time a donor was hemodiluted, received massive transfusion, or has discrepant ABO results.

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