



Matching organs. Saving lives.

CONFIDENTIAL MEDICAL PEER REVIEW

January 18, 2019

VIA SECURE EMAIL

[REDACTED]
CEO/President
OPTN/UNOS Representative
We Are Sharing Hope SC
[REDACTED]

[REDACTED]
Medical Director, Organ Division
We Are Sharing Hope SC
[REDACTED]

Dear [REDACTED]:

As you know, UNOS' Member Quality Department staff has been reviewing the blood typing and transplant of incompatible organs from donor [REDACTED]. The Membership and Professional Standards Committee (MPSC) leadership, including the Vice Chair, Chair of the Performance Analysis and Improvement Subcommittee (PAIS), and Chair of the Policy Compliance Subcommittee (PCSC), along with the OPTN President are reviewing the information that We are Sharing Hope SC (SCOP) has submitted to this date, in a blinded fashion. The leadership group has requested additional specific information and requested that the program participate in an informal discussion to discuss this case.

In order to facilitate a dialogue and for the MPSC to better evaluate the issue, the Committee leadership requests that SCOP participate in an informal discussion with the MPSC. This informal discussion will take place via conference call. UNOS staff will work to set up the call as soon as possible.

MPSC Concerns

The MPSC leadership was concerned by the failure of SCOP's staff and AOC to recognize the potential safety consequences of indeterminate blood typing issues. The group was concerned with the 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. Finally, the group was particularly concerned that SCOP did not

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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.

In an effort to mitigate the risk to patient health and public safety, the MPSC requested that SCOP immediately do the following:

- For every donor with a blood typing sample that is hemodiluted for the primary or confirmatory draw, the OPO must:
 - Send the case to the AOC and Medical Director for review prior to assigning ABO
 - Communicate to all receiving transplant centers that the ABO has been determined using a hemodiluted sample
- Using defined clinical triggers, develop an event-driven algorithm that will automatically prompt mass transfusion cases for review by the AOC and Medical Director.

These actions must be completed until an MPSC-approved protocol is in place.

The MPSC has also requested that SCOP 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.

Informal Discussion Timelines

Informal discussions are described in Appendix L of the Bylaws, which can be accessed on the OPTN website at <http://optn.transplant.hrsa.gov>. Informal discussions are intended to provide the MPSC and member an opportunity to openly discuss the review and seek feedback. If your institution wishes to participate in the informal discussion, please submit written notification to [REDACTED] Compliance Operations Analyst no later than **Tuesday, January 22, 2019**, to [REDACTED]

The informal discussion schedule will include 10 minutes for your presentation and 15 minutes for a question and answer period with the MPSC. After the call, the group will report its recommendation to the MPSC. We will notify you of the outcome as soon as possible after the MPSC's deliberations.

Please submit any additional documentation you would like the participants to review prior to the informal discussion as soon as possible. The MPSC will provide a deadline for additional documentation after the call.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Organ Review Boards must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

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If you have any questions or concerns, or need any additional information regarding this issue, please contact [REDACTED]

Sincerely,

[REDACTED]
[REDACTED]
Vice Chair, OPTN/UNOS Membership and Professional Standards Committee
[REDACTED]