

**OPTN Operations and Safety Committee
Organ Packaging Workgroup
Meeting Summary
August 28, 2020
Conference Call**

Luis Mayen, Chair

Introduction

The Organ Packaging Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 08/28/2020 to discuss the following agenda items:

1. Recap of 7/24 Meeting
2. Discussion: Potential Factors Contributing to Frozen Organs
3. Discussion: Organ Procurement Organization (OPO) Packaging Protocols

The following is a summary of the Workgroup's discussions.

1. Recap of 7/24 Meeting

The Workgroup reviewed the discussions from the previous meeting.

Summary of discussion:

Takeaways of 7/24 meeting

- Reviewed different variations in organ packaging techniques
- Reviewed current data and identified the need to further evaluate packaging practices across OPOs

There were no questions or comments.

2. Discussion: Potential Factors Contributing to Frozen Organs

A subject matter expert (SME) presented potential factors that may contribute to frozen organs.

Summary of discussion:

The SME reviewed the processes of how water and cells freeze as well as other potential factors of damage. The SME expressed the main concern, in regards to frozen organs, is the concentration of solutes in saline, which contribute to freezing points. The SME explained that if the saline solution is not properly made, then the addition of ice to the saline solution will cause lower temperatures than the freezing temperature of the preservation solution in which the organ is kept. Additional concerns expressed by the SME were fluctuations in refrigeration temperatures.

The Workgroup Chair asked what is recommended in place of saline solution in order to maintain temperature. The SME responded that pure water and ice will keep the temperature between zero and four degrees Celsius, which is what is needed for preservation.

3. Discussion: Organ Procurement Organization (OPO) Packaging Protocols

The Workgroup reviewed protocols submitted by OPOs.

Summary of Discussion:

The Workgroup Chair discussed the variations between OPO packaging protocols, specifically highlighting the differing specifications regarding use of saline solution.

The Workgroup Chair asked members if the differences in OPO packaging protocols are substantial enough to warrant standardization via policy or guidance. The Workgroup Chair expressed that the use of saline seems to be a patient safety issue, which they believed warrants a policy.

The Operations and Safety Committee (OSC) Chair inquired whether there was value in standardizing packaging protocols so programs would know which layers were sterile. When considering the increase of broader distribution, this is a valid suggestion.

HRSA representative asked how temperature is maintained once an organ is packaged. The Workgroup Chair responded that OPTN policy requires three layers, one of those being a rigid container. The Workgroup Chair explained that all of those three layers are placed in to a cooler and surrounded by ice. The HRSA representative asked for the rationale in the use of saline. The OSC Chair responded that OPOs want to ensure a constant temperature throughout, so they fill the air pockets. Saline is usually the most accessible solution to use to fill these air pockets.

Members agreed that policy could be changed to address the problem without being too prescriptive. Additionally, creating a guidance document of best practices that includes diagrams for reference.

There were no additional comments or questions. The meeting was adjourned.

Next steps:

The Workgroup seeks to gather more data and engage additional stakeholders to gather feedback.

Upcoming Meetings

- September 25, 2020 (teleconference)
- October 23, 2020 (teleconference)

Attendance

- **Workgroup Members**
 - Christopher Curran
 - Luis Mayen
 - Melissa Parente
- **HRSA Representatives**
 - Arjun Naik
 - Marilyn Levi
 - Raelene Skerda
- **UNOS Staff**
 - Amanda Macchi
 - Craig Connors
 - Joann White
 - Katrina Gauntt
 - Kristine Althaus
 - Leah Slife
 - Matthew Prentice
 - Meghan McDermott
 - Peter Sokol
 - Nicole Benjamin
- **Other Attendees**
 - Boris Rubinsky
 - Gideon Ukpai