

**OPTN Operations and Safety Committee
Organ Packaging Workgroup
Meeting Summary
September 25, 2020
Conference Call**

Luis Mayen, Chair

Introduction

The Organ Packaging Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 09/25/2020 to discuss the following agenda items:

1. Recap of 8/28 Meeting
2. Discussion: Organ Procurement Organization (OPO) Packaging Protocols

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

1. Recap of 8/28 Meeting

The Workgroup reviewed the discussions from the previous meeting.

Summary of discussion:

Takeaways of 8/28 meeting

- A subject matter expert (SME) reviewed potential contributing factors and identified saline as such
- Discussed OPO Packaging protocols and identified use of saline to be commonly used in packaging protocols
- Discussed potential policy modifications and guidance

There were no questions or comments.

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

The Workgroup reviewed OPO packaging processes.

Summary of Discussion:

A member shared that within their donation service area (DSA) their packaging procedure requires the Nalgene container to be filled with a UW-like solution, and then the kidney placed within that. The Nalgene contained then gets wrapper in two sterile bags. The member stated that they have not had any problems with frozen organs reported to them. The Workgroup Chair asked the amount of UW that is used to fill the Nalgene container. The member will find out. Another member mentioned their packaging techniques are similar and they use one liter of UW. The member stated they have not experienced any issues with frozen organs either.

Another member shared they have not experienced any instances of frozen organs. The member stated that their practice was similar to the aforementioned packaging procedure. The member added they experienced an issue where all three sterile barriers were compromised because the packaging supplier changed their products to be thinner as well as the Nalgene warped due to steam cleaning. Because of this situation, the packaging procedure changed to place the organ in a sterile bag with packaging

solution, then place that into a sealed Nalgene container, which is then placed in an outer, third sterile bag. The member stated that this procedure change occurred as a way to protect the innermost sterile barrier which holds the organ. The Workgroup Chair asked if additional liquid was placed inside the Nalgene to fill any gaps. The member responded that they do not place anything additional between the bag with the organ and the inside of the Nalgene container. The member explained that it is difficult to ascertain if there is a leak from the inner most bag, if the Nalgene is also filled with liquid.

The Workgroup Chair shared that they also experienced warped Nalgenes. The Workgroup Chair stated that one time a warped Nalgene container leaked, which caused the organ to arrive with about half of the original packaging solution. This situation caused the packaging procedures to change to the organ placed into a sterile bag, which is then placed in a Nalgene container, then wrapped in an outer, third sterile bag. The Workgroup Chair explained that the space between the inner bag and the Nalgene container is filled with slush. The Workgroup Chair added that they have seen at least three frozen kidneys.

Another member explained their organization uses four layers. The kidney is placed into its own bag with about 500 ccs of UW. The bag with the organ is placed into a bag filled with slush and about 200 cubic centimeters (ccs) of saline. This is placed into the Nalgene, which is then wrapped in an outer, fourth bag. The member stated that they had experienced one liver which had crystals. The formation of crystals was attributed to not enough saline added to the second inner bag. Recently, a kidney was reported to have crystals on the outer fat layer of the organ. The member wondered whether the size of the container and its volume of ice would have an impact on freezing organs.

A member stated that they have witnessed some kidneys arrive in containers used for heart or pancreas. The member added that there are two bags inside the container, and the container itself is used as the outer, third layer.

Another member shared their experience with packaging thoracic organs. The member stated that the thoracic organs are placed in a bag with packaging solution, which is placed in another bag with saline and slush. That is then placed in a container with more saline and slush. The member stated that saline is heavily used in these packaging procedures, yet there are not instances of frozen thoracic organs. The member wondered if time is a contributing factor instead. A member agreed that thoracic organs are contained within their packaging for a much short time than kidneys. Another member asked if the Workgroup could look at data on frozen organs to analyze the timeframes. Staff will look into it.

A member stated that their organization sometimes sends lungs to XVIVO in Toronto, Canada for aggressive lung placement. The member wondered if they had experienced any issues with ice crystallization or partially frozen organs since the transport time is much longer.

Another member wondered whether there is data or research to show the reasoning behind the use of saline in packaging. The Workgroup Chair stated that the SME, from the 8/28 meeting, recommended using pure water and ice, and to be mindful of the saline concentrations because the higher the concentration the more likely it is to decrease temperatures. The Workgroup Chair added their use adding additional liquid is based on assumptions.

A member mentioned their experience using the GPS tracking system for organ transport. The system measures temperature and the member stated that it showed no fluctuations in temperature. The member stated they package their organs with UW and place slush to surround it. The member wondered whether, based on this data, there should be recommendations on how much slush to use in packaging. The Workgroup Chair stated that taking the variation out of measurements could be potentially useful.

Another member stated that there are OPOs across the nation that have their individual packaging procedures which have not led to any frozen organs. The member emphasized it is hard to know what variable is causing frozen organs when there are so few instances and so many packaging variations. The member warned that standardizing packaging procedures will likely result in push back from the OPO community.

A member asked if National Kidney Registry (NKR) has provided any data whether they have experienced frozen organs in their exchanges. The Workgroup Chair stated that this has not been solicited but they can be contacted.

The Workgroup Chair asked whether any of the reported frozen organs have been from a living donor. Staff responded that the reported frozen kidneys were all deceased donor organs. Staff added that the data that is available is not required so it does rely on the willingness of organizations to self-report. Another member asked whether there was commonality in transportation mode in the reported frozen organs. Staff responded that there was no commonality in transportation mode. A member asked whether there was commonality in weather, time of year, or region. Staff responded that there does not look to be any apparent trend.

Another member asked if there is a mechanism in which non-transplantable kidneys can be utilized to research certain types of organ packaging techniques. A member agreed this would be a great way to gather data.

A member stated that another variable is how much ice is placed into the donor during recovery. The member wondered whether some of the frozen kidneys are in the cavity longer, and thus surrounded by ice longer. This could contribute to the organ being colder when initially placed into the packaging than others.

The Workgroup Chair stated that since the data is limited due to underreporting, a potential policy solution could be to require mandatory reporting to better understand the situation. Members agreed with this idea.

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

Next steps:

This project will be presented to the Policy Oversight Committee on October 14, 2020.

Upcoming Meetings

- October 23, 2020 (teleconference)

Attendance

- **Workgroup Members**
 - Benjamin Helmers
 - Charles Wainaina
 - Greg Abrahamian
 - Joanne Oxman
 - Luis Mayen
 - Marc Ducrow
 - Meg Rogers
 - Melinda Locklear
 - Melissa Parente
 - Richard Anderson
 - Vandana Khungar
- **HRSA Representatives**
 - Chris McLaughlin
 - Marilyn Levi
 - Raelene Skerda
- **UNOS Staff**
 - Emily Womble
 - Joann White
 - Katrina Gauntt
 - Kristine Althaus
 - Lauren Motley
 - Matthew Prentice
 - Meghan McDermott
 - Nicole Benjamin