

**OPTN Operations and Safety Committee
Organ Packaging Workgroup
Meeting Summary
July 24, 2020
Conference Call**

Luis Mayen, Chair

Introduction

The Organ Packaging Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 07/24/2020 to discuss the following agenda items:

1. Overview/Recap of 5/29 Meeting
2. Standards in Kidney Packaging
3. Data Review and Request

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

1. Overview/Recap of 5/29 Meeting

The Workgroup reviewed the discussions from the previous meeting.

Summary of discussion:

Takeaways of 5/29 meeting

- Members discussed experiences with frozen organs and inconsistencies in packaging techniques
- Members discussed possible reasons for partially or fully frozen organs
- Current policy on organ packaging was reviewed
- More data and information is needed before determining an approach to address this issue

There were no questions or comments.

2. Standards in Kidney Packaging

A subject matter expert (SME) presented standards in kidney packaging techniques.

Summary of discussion:

The SME reviewed packaging materials, steps to packaging kidneys, differences in packaging techniques, and differences in shipping methods.

A member stated that each organ procurement organization (OPO) has slightly different packaging techniques but has not experienced the procuring surgeon packaging organs. The SME responded that their experience involves procuring surgeons packaging organs. Another member stated that their OPO packages the kidney. The member stated their OPO uses a rigid container with cold UW, which sometimes includes slush, then two sterile bags.

Another member asked what solution is used to submerge the kidney during the packaging process. The SME stated their experience is with UW but that could vary depending on the OPO. The SME explained that with the packaging of the sister kidneys, in which one froze, each kidney was submerged in one liter of UW.

Both kidneys were placed on the pump after the OR, and then into coolers before being transported back to OPO's building where they stayed for a few hours. The kidneys were accepted by the same transplant center and both were individually packaged by the same person, in their own shipping containers, each with one liter of UW. Both packages of UW that were used had the same lot number and same expiration date. One kidney froze, one did not. A member asked where the UW was stored. The SME responded that their UW is stored in a refrigerator that is kept between two and eight degrees Celsius. Another member asked if there were differences in the ice that was used. The SME responded that, after this incident, their OPO received a recommendation to discontinue the use of the large block ice and switch to pellet ice.

The Workgroup Chair asked about the freezing point of UW. The SME replied that they did not know the freezing point but the recommendation was to keep the UW at room temperature until it is being prepped for use. The SME's experience in prepping UW for use is to put it in the refrigerator to bring it to that same temperature, which is between two and eight degrees Celsius.

Another member asked about the temperature of slush when it is placed in the packaging. The SME explained the different types of slush that are utilized, such as bricks of ice and saline slush. The member responded that the different ways to create slush results in different temperatures of the slush.

A member asked if there are instances when saline slush is placed in the shipping container. The SME responded that would not happen but saline slush could be added between a closed rigid container and an outside isolation bag. The Workgroup Chair clarified that everything inside the three barriers is sterile, including the ice.

Another member asked if saline is being used in packaging. The SME responded that saline is used in packaging, but not directly in contact with the organ. The member asked if it was standard of practice in every OPO to use UW or HTK solution in the isolation bag with the kidney. The SME responded that they could not guarantee this is every OPO's practice, but it has been their experience.

Another member mentioned their OPO used to use saline but changed policy after ice crystals were found on a kidney. The member read their policy which outlined kidneys placed in a bag with UW, which is then placed in a second bag with more UW. That is placed into a rigid container, and the rigid container is then placed in a third bag. Their policy notes that slush should not be placed inside the rigid container.

A member mentioned that after an experience with a frozen heart, the OPO switched to using Paragonix SherpaPak, which allows members to program exact temperatures for transport. The Workgroup Chair asked if the SherpaPak requires a member to operate it. The member responded that the heart is connected to the SherpaPak and becomes suspended in the saline, which maintains a programmed temperature so it does not require continuous operating.

Another member mentioned that in their twenty years of experience they have not encountered a frozen kidney. The member stated that it seems like frozen organs are a rare problem and that the majority of packaging techniques work.

A member asked if all of the presented and discussed packaging techniques comply with UNOS policy. The Workgroup Chair responded that these varying packaging techniques do comply with UNOS policy and it highlights that OPTN packaging policy does not require specifics. The Workgroup Chair cautioned the Workgroup of proposing language that is too prescriptive so that OPOs are not restricted in the resources they are able to obtain. A member asked if the Workgroup can request each OPO's packaging policies for review. The Workgroup will explore this option.

Another member asked if the Workgroup was able create a pilot for standardized packaging techniques. Staff responded that this may not be able to be a pathway but the Workgroup could analyze specific policies to see where the opportunity to create packaging standards exists.

3. Data Review and Request

The Workgroup reviewed the voluntarily reported frozen organs, all reports were kidneys.

Summary of Discussion:

A member asked why reporting of frozen organs is voluntary. UNOS staff responded that the only event that OPTN policy requires members to report are potential donor-derived disease transmission and living donor events. Any other reporting is voluntary in order to promote process improvement.

Next steps:

- Members will continue to consider potential data requests.

4. Next Steps

Members will request packaging techniques from different regions' OPOs.

Upcoming Meetings

- August 28, 2020 (teleconference)
- September 25, 2020 (teleconference)