

**OPTN Operations and Safety Committee
Organ Packaging Workgroup
Meeting Summary
May 29, 2020
Conference Call**

Luis Mayen, Workgroup Chair

Introduction

The Organ Packaging Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 05/29/2020 to discuss the following agenda items:

1. Project Overview
2. Discussion: Project Outline/Goals
3. Next Steps

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

1. Project Overview

The Workgroup reviewed the background and goals of the project as well as processes for recommending projects to the Policy Oversight Committee (POC).

Summary of discussion:

Eight cases of partially or fully frozen kidneys have been reported. The root cause of freezing has not been determined but believed to be saline in the packaging mixed with ice. The Workgroup will analyze organ preservation processes and develop a project outline to address this issue.

2. Discussion: Project Outline/Goals

The Workgroup discussed their experience with organ preservation and packaging procedures as well as reviewed *OPTN Policy 16.3: Packaging and Labeling*.

Summary of discussion:

A member stated that within their Donation Service Area (DSA) they have encountered some issues, but these occurrences happened too infrequently to identify the root cause.

Members agreed with this and gave further examples, such as the appearance of crystals on organs due to the cold temperatures of the packaging. Members questioned whether the formation of crystals could be caused by freezing or the placement of ice in the packaging.

Some members expressed experiences where they discovered slush ice in the packaging with not enough liquid, which then could cause freezing. A member added that in their experience, the ice they used in their packaging was negative twenty degrees and they found this to be the root cause of a particular frozen organ incident.

The Workgroup Chair asked members if they were familiar with the packaging of kidneys. Members agreed that there is variability in organ packaging processes. A member detailed a standard organ packaging method. UW Solution will be decanted into a bag and the organ placed directly into the bag. This bag will be placed into a rigid container and sometimes, in order to prevent air pockets and ensure

the organ is maintained cold, pieces of the frozen saline are added to fill in any gaps. Some members also expressed concern on whether the addition of frozen saline could potentially be the cause of organs becoming either partially or fully frozen.

A member asked if there is enough information to know which packaging procedure is correct. Another member responded that if they are able to collect data on incidents and identify the variations in packaging, they could potentially find answers. A member asked if there were any studies or experiments that analyzed packaging techniques. Members were not aware of any.

A member asked if it was possible to have a group check organ temperatures to gather data in an effort to determine a root cause. Members agreed that this would be very helpful considering the gaps in data, although a widespread study would pose difficulties.

Another member suggested gathering information on past frozen organ cases and use that data to examine root causes in order to understand policy options. A member asked if it was possible for the Workgroup to receive all records of frozen organs. UNOS staff will look into this further to see if any additional information is available. A member stated that even if the Workgroup is unable to determine a root cause, education on past packaging accidents could be a viable and helpful approach.

A member asked if the scope of this project is all organ packaging or solely kidneys. A member responded that the data will help give a better understanding, but most of the cases discussed have been kidney and liver. A member asked if pancreas is included since the packaging is similar. A member responded that they have heard reports of pancreas packaging issues and it is worth exploring issues with other organs. A member asked if fresh tissue grafts are similar enough to be included. Members did not know the answer to this but agreed that tissue has a different tolerance for preservation than other organs so it might not be applicable.

A member stated that while *OPTN Policy 16.3: Packaging and Labeling* appears prescriptive, there is a lot of variation that could align with the policy language resulting in different procedures across members. The policy language currently requires a triple sterile barrier to protect organs. Members discussed variations in organ packaging among OPOs and suggested the possibility of standardizing these requirements by providing more detailed information in policy. The member pointed out this policy does not mention saline.

Another member asked if a presentation on the standard types of organ packaging would be helpful for the Workgroup members at the next meeting. Members agreed this training could be helpful.

Next steps:

- UNOS staff will look into any additional reports of partial or frozen organ cases (not limited to kidneys and livers).
- The Workgroup will continue their discussion on packaging procedures.

3. Next Steps

The Workgroup discussed next steps.

Summary of Discussion:

The Workgroup agreed that more information would be needed to fully assess the problem. A member mentioned surveying Organ Procurement Organizations (OPOs) to review Standard Operating Procedures (SOPs) as it pertains to organ preservation and packaging.

Before determining next steps, a detailed understanding of organ preservation would be beneficial first before determining how best to address this issue. A member suggested reaching identifying and

reaching out to subject matter experts (SMEs) to present their experiences and findings in organ preservation practices. It was also suggested that it may be helpful to include representation from the Organ Procurement Organization (OPO) Committee and the Association for Organ Procurement Organizations (AOPO).

Next Steps:

- UNOS staff will work with the Workgroup Chair to do outreach for SME's to provide education to the Workgroup on organ preservation.

Upcoming Meeting

- July 24, 2020 (teleconference)
- August 28, 2020 (teleconference)