

# Operations and Safety Committee Update

Phillip C. Camp, Jr., MD  
Chair, Operations and Safety Committee

OPTN/UNOS Board Meeting  
June 28-29, 2011

**OPTN**



# Background and Goals

Reviewing current OPTN/UNOS processes and initiatives aimed at improving patient safety:

- Evaluating systems to improve quality, safety, outcomes
- Considering ways to disseminating quality practices

To increase the general knowledge about patient safety events, their causes, and strategies for prevention in an effort to have positive impact on improving patient care, treatment, and services

- Consider how to report data back to members
- Provide resources and tools for members to use

# HUMAN FALLIBILITY

“It doesn’t matter how smart you are, how careful or conscientious you are, how well rested you are. As a human handling data, you WILL make mistakes, and the way you really solve that is to build robust systems that make it hard to do wrong, easy to do right.”

*Brent James, Intermountain Health Care, SLC*



# Where Does Transplantation Fit In?

- In its report *To Err Is Human: Building a Safer Health System*, the IOM estimated that as many as 98,000 hospitalized Americans die each year—not as a result of their illness or disease, but as a result of errors in their care (IOM, 2000).
- Federal initiative - to reduce medical errors and improve patient safety in federally funded health care programs, and by example and partnership, in the private sector.
  - Why do such errors occur;
  - How to prevent these errors;
  - Collect data on patient safety (PS);
  - disseminate PS information to consumers and providers (Clancy and Scully, 2003).

## SAFETY CULTURE

The product of individual and group values that commit to the prevention of harm

### REPORTING CULTURE

Individuals feel Free to "confess" errors

### JUST CULTURE

Defined by how an organization handles blame and punishment

### LEARNING CULTURE

Commitment to learning from mistakes & near misses to correct hazards and dangers

### FLEXIBLE CULTURE

One that adapts to changing demands and successfully manages the unexpected.

Adapted from work of James Reason

# OPTN Patient Safety Reporting

## Patient Safety reporting (implemented 2006)

- Disease Transmission Events (mandatory)
  - Living Donor Adverse Events (mandatory)
  - Patient Safety Situations (voluntary)
  - Best Practices (voluntary)
- 
- Other pathways exist for data or issues to be reported to the OPTN

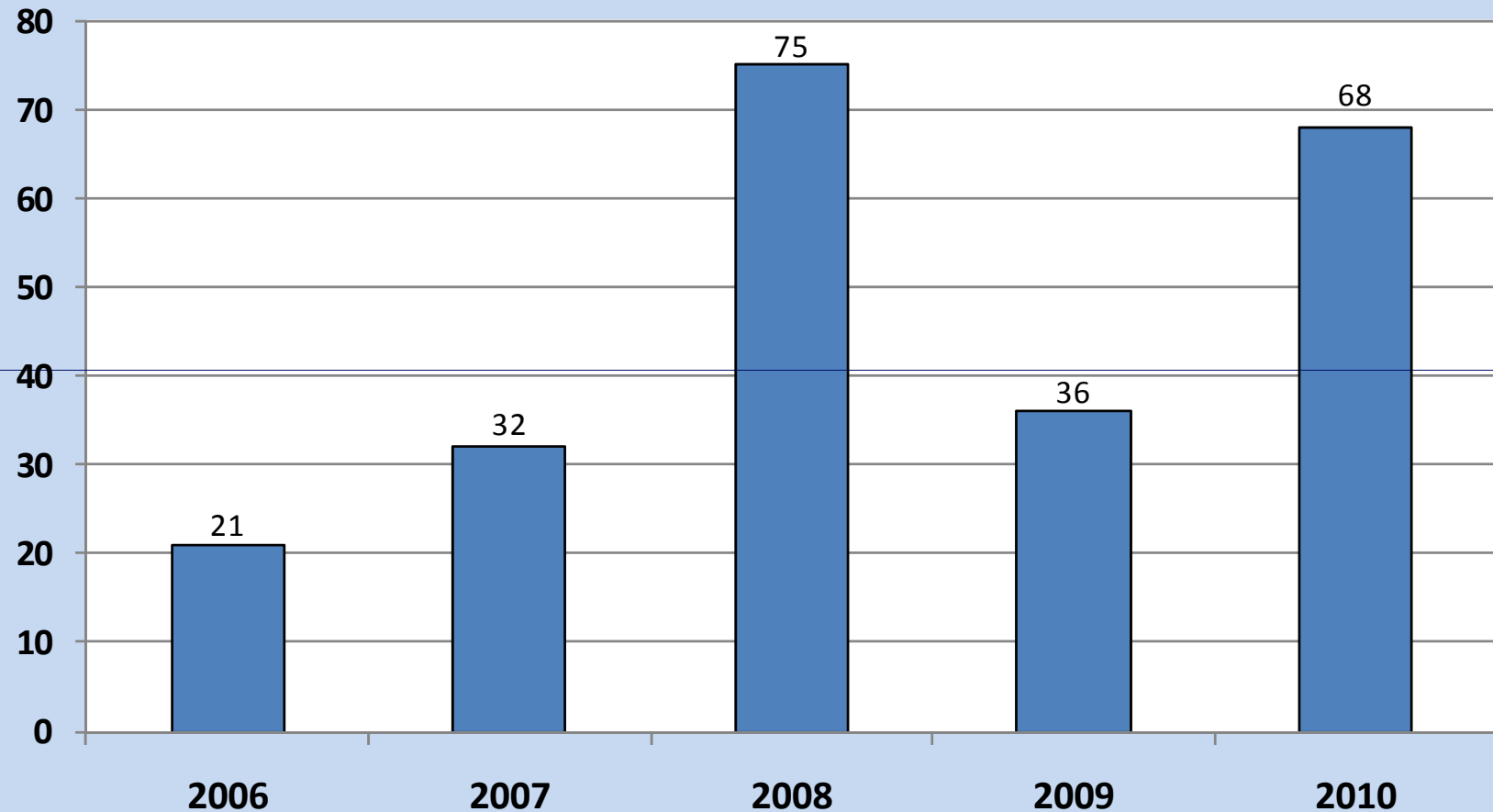
## 4 Core Principles of a Patient Safety Reporting System (WHO)

- Fundamental role - enhance safety by learning from failures of the system.
- Reporting must be safe. There must be an established Just Culture by the organization.
- Reporting is only of value if:
  - Leads to a constructive response
  - Feedback of findings from investigation and data analysis
  - Recommendations for changes in processes or systems.
- Analysis, learning, and dissemination of lessons learned.

## Trends in Patient Safety Situation Reporting

Reported to PSS

Graphic 2



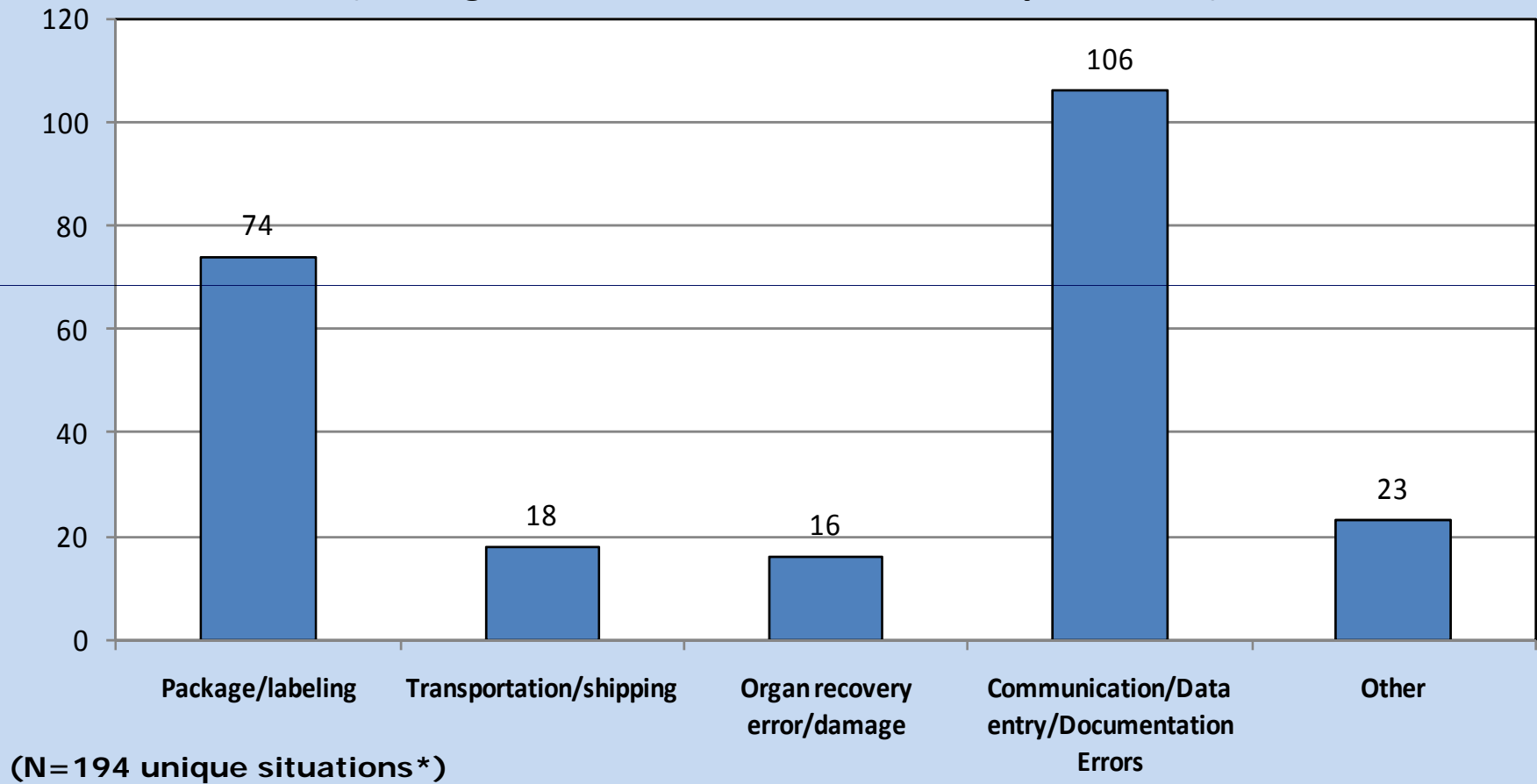
(N=232)  
(Excludes events incorrectly reported into the safety situation portal, such as potential disease transmissions, as well as other "cancelled" events (such as duplicates). )

➤ Sizable drop-off in reporting in 2009; reporting back up in 2010.



# Reported Patient Safety Situations by High-Level Category

Through the PSS Portal – March 2006 – September 30, 2010

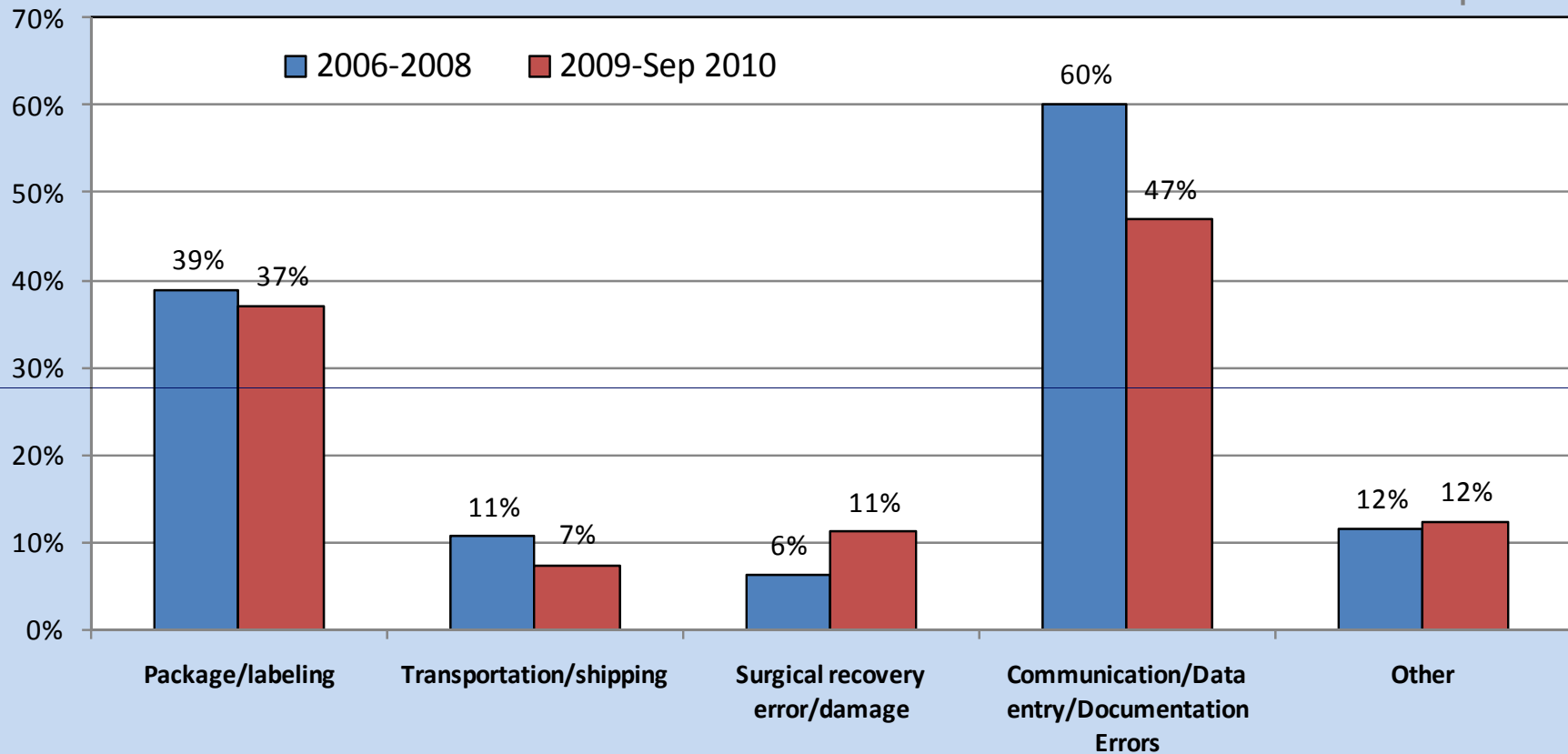


*(\*Some safety situations fall in multiple categories.)*

## Reported Patient Safety Situations by High-level Category and Era

Through the PSS Portal – March 2006 – September 30, 2010

Graphic 6



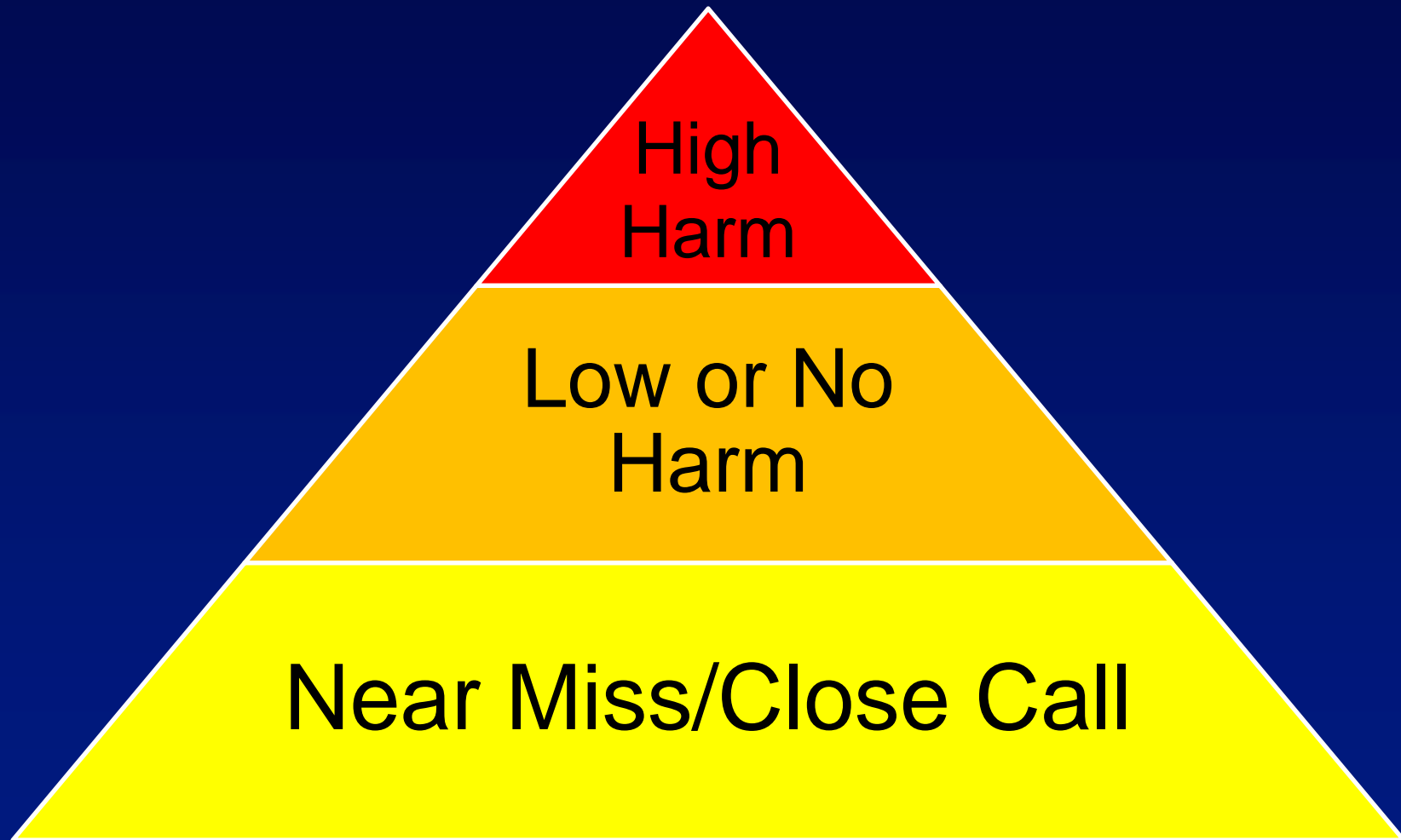
- Reported communication/data entry/documentation errors were most prevalent in both eras, though less so in recent era.
- Little change in packaging/labeling events frequencies.

*(Percentages exceed 100 since some events fall into multiple categories).*

# Why Report Safety Events to the OPTN?

- Decrease events that can cause patient harm (i.e. ABO incompatibilities);
- Decrease “same” mistakes that occur repeatedly within the system (i.e. packaging and labeling errors);
- Community receives useful information gained as a result of analyzing the event or similar events;
- Aggregate data made available to the community.

# Anticipated Types of Safety Events Reported



# Current Status of Reporting to OPTN

- Reporting mechanisms currently exist;
- Data analysis of a few groups of events is taking place to determine trends/patterns (i.e. DTAC, OSC, MPSC, etc.);
- No centralized database for aggregate of all safety events; and
- Limited reporting of lessons learned/solutions

# How to move forward?

Improve data reporting by creating a Just Culture:

- Provide responses/actions to members in a way that shows desire to see the system work more safely;
- Encourage members to be proactive in root cause analysis (RCA) and action plans;
- Provide tools and resources to conduct RCA and action plans'
- Create culture of expectation for self monitoring (Quality Assessments and Improvement)

# Expected Outcomes

- Increase the culture of safety, safety event reporting and analysis -
  - Lower the number of high harm events;
  - Increase the number of “lesser” harm event reporting;
- Increase in proactive reports of potential policy violations that include RCA and action plans with internal quality and performance monitoring by the member;
- Provide mechanism to proactively identify and solve problems;
- Create resources for improvement for community
- Efficient real-time analysis of safety data – address gaps in the system or policy.

# Reaching Goals to Create a Culture of Safety

- First edition of Patient Safety newsletter made available in April 2011;
- Developing a repository of searchable best/effective practices and resources for members to choose from;
- Proposing modifications to the patient safety event reporting system to enhance trends and patterns analysis.



# Recent System Improvements - Through Analysis of Safety Data

- Packaging and Labeling
- Vessel Recovery and Storage
- ABO Subtyping

# **Operations and Safety Committee: Proposed Recommendations for Policy Regarding Vessel Storage and Transplant**

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# Background

In September 2009, a donor-derived transmission of hepatitis C was identified during review of a potential disease transmission case by DTAC. The transmission occurred after a stored hepatitis C antibody positive deceased donor extra vessel was inadvertently transplanted into a living donor liver recipient that was hepatitis C negative. The extra vessel was appropriately labeled per OPTN policy, but the transplant center **did not** recognize that the label indicated the extra vessel to be hepatitis C antibody positive at the time of transplant.

## Background (2)

In response to this event, O&S Committee was directed to assemble a work group with representatives from other OPTN committees to review current policy requirements related to vessel recovery, storage, and transplant to assess whether current policy had failed to protect the recipient of the extra vessel.

- The Work Group included:
  - Infectious Disease (ID) physicians (DTAC)
  - Transplant Administrators (TAC)
  - OPO representatives (OPO)
  - Thoracic and abdominal surgeons (Liver, Kidney, MPSC)
  - Pediatric surgeon representation (Peds)
  - CDC representatives

# Background (3)

Several areas of concern:

- No requirements to verify compatibility of donor vessel(s) with the recipient;
- Hepatitis positive vessels and tissues are often stored within the same refrigerated system as other negative serology vessels: easy to **accidentally** obtain vessels not compatible for the recipient;
- Policy allows storage of hepatitis positive vessels; and
- No standard definition of “extra vessel”

## Options Considered by The Committee

- Special labeling for HCV (+)/HBV surface antigen (+) stored extra vessels;
- Separate storage refrigerator for HCV (+)/HBV surface antigen (+) extra vessels;
- Prohibiting storage of HCV(+)/HBV surface antigen (+) vessels;
- Consider the need for a standardized definition of “extra vessel.”

## The Committee's Response to the Options...

- Special labeling requirements for hepatitis + vessels was initially rejected - OPTN data reviewed in April 2010 shows > 50% of safety situations reported to the OPTN related to errors in packaging and labeling of organs.
- A separate storage site was rejected - too costly and cumbersome for programs to implement;
- Request data to identify if there would be an issue of supply due to a proposed restriction of HCV Ab + and HBV surface Ag + vessel storage; and
- Discuss with experts, in use of vessels, appropriate definition of “extra vessel” to decrease confusion in reporting vessel disposition.

## HEPATITIS POSITIVE and HIGH RISK EXTRA VESSELS TRANSPLANTED 2008-2009

| <i>Transplanted into...</i>   | HCV+ | HBV Core+ | High Risk |
|-------------------------------|------|-----------|-----------|
| Same Recipient as Solid Organ | 20   | 33        | 122       |
| Another Recipient             | 4    | 4         | 22        |

- There were **4** Hep C+ vessels transplanted into “secondary” recipients during this timeframe.
  - ✓ 2 recipients Hep C – and two Hep C + pre-txp
  - ✓ Of the 4 events, **one** resulted in **confirmed transmission**.
  - ✓ **2** hepatitis C + vessels txp'd in hepatitis C – recipients with no transmission - **near misses**.
- **No** HBsAg + vessels txp'd in a secondary recipient.



# Evaluation of Impact on Transplant Centers

## Vessel Supply & Demand Analysis -

- Purpose: evaluate if enough vessels would be available to meet the needs of recipients of hepatitis + organs, – if storage HCV+ and HBV S Ag+ vessels were prohibited.
- Assess number of vessels sent to each transplant center within each DSA (supply); number of transplants utilizing HCV + or HBV s Ag+ organs (potential demand).
- A “vessel shortage” is defined as needing a donor vessel for post-transplant vascular revision in a recipient of an HCV+ or HBV s Ag+ organ, but no compatible donor vessel is available.

***\*\*\*Full report on supply and demand begins – Tab G, page 43***

## Vessel Supply & Demand Analysis Results

- Results: Analysis showed that it is likely that about 1 DSA would experience a vessel shortage with a one year period of time.
- Conclusions: Widespread shortages are unlikely, though a small number of shortages could theoretically occur.
  - If a shortage occurs, sharing of vessels between centers and synthetic vessel substitutes can be used (although inferior to donor vessels).
  - The benefits of prohibiting storage of these vessels outweighs the potential for disease transmission, since widespread shortages not expected.

## Proposed Definition of Extra Vessel

“Extra vessels” are those vessels taken during the Organ procurement process of deceased or living donors with the intent for use as a vascular conduit\*. Anything directly attached to the organ (without surgical modification) to be transplanted is not considered an “extra vessel”.

*\*Vascular conduits are routinely taken from areas not immediately connected to the transplantable organ (i.e. iliac artery or vein, carotid artery or jugular vein, etc.) and are necessary to reconstruct the vasculature of the transplanted organ.*

# **Recommended Policy For Public Comment**

## **POLICY 5.10.1 Vessel Transplant -**

- **Require timeout prior to implant of vessel(s):**
  - **Verify ABO, serology results, container contents, date of expiration and the UNOS Donor ID of the donor vessel with ABO and all serology results of the intended recipient. Document the verification.**
- **Remove requirement for implanting TXC to provide detailed explanation to OPTN when hepatitis + vessels are transplanted into a secondary recipient .**

## **POLICY 5.10.2 Vessel Storage -**

- **Prohibit storage of HCV Ab positive and HBV surface antigen positive extra vessels.**

# **Review of Public Comment**

# OPTN Committees' Response to Vessel Proposal

Opposed:

Supported:

Liver/Intestine

DTAC

Pancreas

LDC

Peds

OPO

POC

TCC

TAC

PAC

Minority Affairs

# Regional Response to Vessel Proposal

## 7 - Opposed:

Region 1

Region 3

Region 4

Region 7

Region 9

Region 10

Region 11

## 4 - Supported:

Region 2

Region 5

Region 6

Region 8

# Individual Responses...Opposed

- HCV - most common indication for liver transplantation - use of vessels after a txp, necessitating storage, is rare but it does occur.
- Having access to vessels can be both graft and life saving.
- Prohibiting storage forces the surgeon to use prosthetic material with higher risk of infection and thrombosis or list the patient for re-transplant (which will use up more livers).
- When needed urgently, having vessels unavailable puts the HCV + transplant patient at risk post-op.
- Rules for labeling, color coded storage containers or alternate storage areas are preferable, HCV infection is not desirable but informed consent should be the criteria for use or disposal.



# Individual Responses...Opposed

- Limit the use of vessels to the primary organ recipient
- The conclusion that these vessels must be discarded because HCV was transmitted, despite no error in labeling, is flawed reasoning.
- Require ABO and serologic compatibility documentation. If this policy goes through as is, it will result in the death of a liver recipient because there is not a safe process for storing hepatitis + vessels.
- With this policy proposal, clinicians are put at risk when they are making life and death decisions for their patients.

# Individual Responses...In Support

- Modest correction to the inappropriate designation of blood vessels, should be regulated under 21 CFR 1271 eliminating this problem.
- No one would want to use vessels from a donor with a high risk of transmitting an infectious disease, proposal is entirely appropriate.
- Organs from a hepatitis C + donor for a hepatitis C + recipient are used, this level of risk is never indicated in the use of donor blood vessels given the likely supply and demand for such tissue.
- The proposed practice was adopted this at our center, initially with resistance, nevertheless, it seems the safest option for all involved to not store these vessels.

# Professional Societies' Response

## ASTS - OPPOSED –

- Reaction to one case of transmission occurring prior to new labeling policies;
- If transplant of HCV + organs is allowable, storage of the HCV + vessels should be allowable;
- Vessels are needed to rescue the organ or patient when there is a vascular complication. Multiple cases have arisen where patients have needed vessels and were not available, whereas disease transmission has occurred once;
- The proposal is designed to improve patient safety but may create more situations where patient safety is at greater risk.

## NATCO - SUPPORT –

- Ensures that the accidental use of HBV + and HCV + vessels does not occur;
- Requiring verification and completion of UNOS labeling information ensures accepting centers, and those who have access or handle vessels, have full disclosure of information.

# CDC's Response

The proposal is consistent with recommendations to be submitted for public comment of 2011 PHS Guidelines for Reducing Transmission of HIV, HBV, and HCV, through Solid Organ Transplantation and MMWR that was published in February 2011:

- 2 near miss events in 2009 - vessels transplanted into sero-negative recipients from sero-positive donors in error, but did not result in transmission;
- Under-reporting is likely substantial, more transmissions may have gone unrecognized;
- Some OPOs perform routine NAT, recommend vessels from a donor who is HCV or HBV NAT + should not be stored, as these results indicate recent infection.

# Amended Proposal Based on Public Comment

## POLICY 5.10.1 Vessel Transplant –

- Require time out to verify vessel(s) ABO, serology results, container contents, date of expiration and the UNOS Donor ID with the ABO and all serology results of the intended recipient prior to implant.
- Remove requirement for implanting TXC to provide detailed explanation when hepatitis + vessels are transplanted in a secondary recipient.

## Policy 5.10.2 Vessel Storage -

- vessels may be stored for use only in the intended recipient and must be labeled with the name of the intended recipient to assess during the time out.

# Resolution S

## **POLICY 5.10.1 Vessel Transplant –**

- **Require time out to verify vessel(s) ABO, serology results, container contents, date of expiration and the UNOS Donor ID with the ABO and all serology results of the intended recipient prior to implant.**
- **Keep the requirement for implanting TXC to provide detailed explanation to the OPTN when hepatitis + vessels are transplanted in a secondary recipient.**

**Questions?**



**Operations an Safety Committee:  
ABO Subtyping Guidance Document**



# Background

Living donor kidney transplant event, June 2008:

- A1 -> O, accelerated rejection. Donor incorrectly subtyped as non-A1. (confirmatory testing was not performed)

Subtyping Work Group with representation from:

- American Association of Blood Banks (AABB);
- Blood bank medical director;
- Histocompatibility laboratory;
- Histo Committee;
- Operations and Safety Committee;
- Other transplant professionals from OPO and TXC.

# Subtyping Terminology

- **A<sub>2</sub> vs non-A<sub>1</sub>**: technically accurate term for A<sub>2</sub> is negative for A<sub>1</sub> or non-A<sub>1</sub>, there is no test for A<sub>2</sub> antigen—only a test for whether the A<sub>1</sub> antigen is present or not, and many other rare subgroups exist (e.g. A<sub>3</sub>, A<sub>int</sub>, etc.).
- Subtype terminology (A<sub>1</sub> and A<sub>2</sub>) should not be confused with the Class I histocompatibility antigens HLA-A1 and HLA-A2.

## Blood Group A and AB Subgroup Determination

|  |   |   |  |
|--|---|---|--|
| A <sub>1</sub> -reactive,<br>synonymous<br>with: | A <sub>1</sub> B-reactive,<br>synonymous<br>with: | A <sub>1</sub> -nonreactive,<br>synonymous<br>with: | A <sub>1</sub> B-nonreactive,<br>synonymous<br>with: |
| A <sub>1</sub> -positive                         | A <sub>1</sub> B-positive                         | A <sub>1</sub> -negative                            | A <sub>1</sub> B-negative                            |
| A <sub>1</sub>                                   | A <sub>1</sub> B                                  | A <sub>2</sub>                                      | A <sub>2</sub> B                                     |

# Subtyping Guidance

- Understanding current laboratory practice for subtyping;
- Appropriate terminology in reporting and interpreting subtyping results;
- Other factors affecting results of subtyping –
  - Donor PRBC transfusions
  - Subtyping of neonates and infants
- Recommendations when ambiguous test results

Resolution language on page 6 of BOD Rpt.  
Guidance Document is Exhibit C, page 96.

**Questions?**



**Thank you!**

