Operations & Safety Committee: Report to the OPTN/UNOS Board

Jean Davis, Chair
Theresa Daly, MS, FNP, Vice-Chair

November 11-12, 2013
Atlanta, GA
Committee Projects

- System to share patient safety data
  - Patient Safety Alert Process Developed
- Patient Safety Newsletter
- ABO Verification
- Electronic Tracking and Transport Update
- Involuntary Waitlist Transfers
System to share patient safety data

- Building a “culture of safety”
- Using safety data to help members learn from mistakes and improve processes
- Sharing effective practices
- Routinely analyzing and publishing safety reporting results and top policy violations
Overall Trends in Reporting

Fig 1: Trends in **Patient Safety Situation Reporting**
(through UNet "Improving Patient Safety" Portal, Mar 2006 - Jun 2013*)

(Prokected)

On pace for a continued increase in reporting in 2013.
IPS and “Other Pathways” Reporting Combined

Fig 6: Reported Patient Safety Situations by High-level Category (through both IPS and "Other Pathways", Jan 2012 - Jun 2013)
N=213 in 2012, N=136 in 2013 (Jan-Jun)

- Communication: 23%
- Testing issue: 16%
- Allocation process: 15%
- Transplant process: 12%
- Data entry issue: 11%
- Labeling issue: 10%
- Recovery process: 9%
- Packaging/shipping: 8%
- Transportation: 1%
- Other: 15%
Data are reviewed within categories

<table>
<thead>
<tr>
<th>Transplant Procedure/Process Issues, by Subcategory</th>
<th>2012</th>
<th>2013*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>other - vessel sharing</td>
<td>11</td>
<td>8</td>
<td>19</td>
</tr>
<tr>
<td>vessels used in a non-transplant patient</td>
<td>5</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>other - recipient not promptly removed from Waitlist</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>complaint about program frequent pursuit of meld exceptions</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>donor/recipient compatibility check not performed</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>other - complaint about overaggressive acceptance of marginal organs</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>other - complaint about poor candidate selection that led to bad outcome</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>other - complaint of poor post-op patient care</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>other - complaint of poor quality organ used for transplant</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>other - delay in listing a patient</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>other - drug recall</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>other - immunosuppression drug recall</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>other - organ discarded due to no surgeon available</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>other - patient not listed promptly</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>other - recipient not removed promptly from Waitlist</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>other - stent left in too long</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>other - vessel destruction not documented</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>transplant procedure/process issue - (no subcategory)</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Safety Alert Process Developed

- Alerts meet the following criteria:
  - Recur in the safety event reporting?
  - Caused or significant potential for harm to patients (death, permanent loss of function)?
  - Caused or a significant potential for impact on the public trust in the OPTN?
  - Is time-sensitive?
  - Significant enough to merit a stand-alone communication?
  - Contain call to action for members?
Patient Safety News

September 2013

In this Issue
The Operations and Safety Committee (OSC) continues to promote a “culture of safety,” using what we have learned from past mistakes and “near misses” to educate members about prevention and effective practices. The committee reviews aggregate de-identified patient safety data reports and other resources every six months to improve transplant systems and processes. As a result of this work, you will read more about the latest patient safety data and identification of extra vessels as an area of concern. In addition, as part of promoting lessons learned, we will highlight some effective member practices.

In other news, the committee continues its work to review ABO verification processes and is conducting a failure modes and effects analysis (FMEA) to identify system issues and gaps. Committee members also participated in the electronic tracking and traceability (ETT) project, which developed and pilot-tested an automated system to generate labels used in organ procurement. Finally, OSC members are working with DTAC to review the newly-released PHS guideline.

Articles
Making safety a part of your culture ................................................................. 1
Creating a ‘culture of safety’ – a priority for the OSC
Focus on documenting dialysis start-date .......................................................... 2
The third most common policy violation
Potential Safety Events involving extra vessels .................................................. 3

Reporting Patient Safety
Use the UNetSM Improving Patient Safety Portal to:
- Report potential donor-derived disease transmission events
- Report patient safety incidents
- Report living donor adverse events
- Access OPTN patient safety contacts

“We want members to report safety situations and then make sure that we use these data so that you can learn from one another and avoid repeating the same mistakes. We want to be proactive versus reactive in making sure that organ transplantation is as safe as it can be.”

Jean Davis

OPTN
Other Steps to Build Culture of Safety and Share Safety Data

- Ongoing safety data presentations and membership outreach with professional societies (e.g. AOPO, NATCO)
- Development of manuscript
- Collaboration with OPO, TAC, TCC
ABO Verification-Failure Modes and Effects Analysis

- Proactive technique to identify process points vulnerable to failure
- Fail points ranked and examined for causes/solutions
- Widely used in industries such as aviation, manufacturing, and health care
- Part of OPTN Strategic Plan
Electronic Tracking and Transport Project (ETT)

<table>
<thead>
<tr>
<th>Field Testing in Progress</th>
<th>July 2013-February 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>LifeSource (MN)</td>
<td>Sep 2013-Nov 2013</td>
</tr>
<tr>
<td>California Transplant Donor Network</td>
<td>Nov 2013-Jan 2014</td>
</tr>
<tr>
<td>LifeLink (GA)</td>
<td>Dec 2013-Feb 2014</td>
</tr>
<tr>
<td>Living Legacy Foundation (MD)</td>
<td>Jan 2014-Feb 2014</td>
</tr>
</tbody>
</table>

- Includes training, proficiency testing, testing on actual donor cases, and 24/7 support from ETT team
Electronic Tracking and Transport Project (ETT): Next Steps

- Complete field testing: Feb 2014
- Application development: May 2014
- Beta testing: Aug 2014
- Application available: Sep 2014
ETT Related Projects

- Limit paper documentation with organ (OPO)
- Modify or remove internal vessels label (OPO)
- National standard for marking organ laterality
Involuntary Waitlist Transfers

- Drafting “tool kit” to assist with information when transplant programs close
- Sections for closing programs as well as programs receiving transferred patients
- Section for patients developed with Patient Affairs Committee
- Will contain requirements, helpful hints, and FAQs
- Developing public comment proposal to collectively transfer groups of patients
Joint Committee Projects

- Joint DTAC-OPO-Operations and Safety Subcommittee
  - 2013 PHS Guideline Review

- Joint DTAC-OPO-Operations and Safety Subcommittee
  - Addressing policy needs for re-running a match run when serologies change (anticipated Spring 2014 public comment)
Projects Awaiting Programming

- Extra Vessels disposition electronic reporting (policy for reporting within 7 days awaiting implementation)
- Enhancements to Improving Patient Safety portal-patient safety situation reporting
- Subtype help language/clarification
Questions?

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