Developing a Revised Organ Verification Protocol

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Context

On average, 79 people receive an organ transplant every day. This totals over 28,000 organ transplants performed in the year 2012 alone. With numbers this high, it is imperative to have a proper labeling and packaging process in place for the procurement of organs. If the safety and wellbeing of a transplantable organ is compromised, the health and vitality of the intended recipient is placed at risk.

The Louisiana Organ Procurement Agency (LOPA) recognized the necessity of having a well-defined verification process for the packaging and labeling of organs recovered for transplant. In 2011, LOPA initiated a Kaizen event to address this issue of organ procurement. This Storyboard outlines the development of a revised protocol to ensure verification and proper labeling of organs recovered for transplantation.

Aim

Clarity the parameters for verification and develop a revised process for the proper labeling and packaging of organs recovered for transplant.

Methods

The planning stage consisted of:
1. Review of previous occurrence report(s) to understand the problem at hand
2. Construction of Root Cause Analyses (RCA) of the issue
3. Baseline OR audits for observation

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<td>36 occurrence reports April 2009, 2013 involving labeling</td>
<td>No further occurrence reports written on labeling for two years</td>
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<td>7 instances of organs delivered labeled incorrectly in 2 years</td>
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Figure 1. Comparison of current baseline measurements with the target level of performance expected as a result of the Kaizen event.

Involving the Experts:

- LOPA management identified seasoned employees who perform these tasks regularly as Subject Matter Experts (SMEs).
- Because of the complexity of the process, groups were limited to two SMEs and three Quality staff members.
- Two groups met on separate days: one group of an APC and an Organ Recovery Coordinator and one group of two Surgical Coordinators.

Figure 3. The roles of the QI team participating in the Kaizen event were explicitly defined as to streamline the development process. These tasks were carried out by means of Root Cause Analyses and Baseline OR audits, corresponding to steps 2 and 3 in the aforementioned planning stage.

Figure 4. During the Kaizen event, the QI team identified several perceived barriers to correct organ labeling. These must be addressed in the development of a successful verification and labeling process.

Figure 5. Clinical staff engaged in process mapping. Quality staff were present to facilitate and record results.

The new Labeling and Packaging Verification process clearly defines verification, staff roles and steps to accomplish verification of information in the O.R. setting. The defined procedure states:
1. A valid source, the OPO's Verification of Organ Labeling and Packaging Form, must be used as the source for comparing donor information for accuracy and verification of proper packaging. The valid source includes: Donor ABO, UNOS ID, Donor DOB
2. Verification of Labeling and Packaging of all required information and specimens to be included with an organ for transplant. This includes, but is not limited to, the verification of the Mini Chart, tissue typing and blood specimens, vessels (internal and external labels), thoracic and abdominal organs (internal and external labels) and biopsy material (when included).
3. Description of the roles of “verifier #1” and “verifier #2.” The communication between both verifiers must be done verbally; no hand gestures or non-verbal cues may be used to acknowledge verification of information.
4. The process must be uninterupted. If an interruption should occur the process must be restarted from the beginning to ensure accuracy of information.

Figure 2. Primary sources of error within the organ procurement process in place prior to the 2011 Kaizen event.

Conclusions

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Roles of the QI team in the development of a revised procurement protocol

- Review materials and process currently used in organ packaging and labeling to determine if they meet UNOS regulations
- Determine improvements to maximize efficiency and minimize errors in packaging and labeling process
- Assess the effects of a varying recovery environment and design a process based on the consistent elements and regulatory requirements.

Figure 4. During the Kaizen event, the QI team identified several perceived barriers to correct organ labeling. These must be addressed in the development of a successful verification and labeling process.

Lessons Learned

- The lack of understanding of the meaning of verification and the lack of an effective verification process lead the OPO to an error.
- The Kaizen event facilitated a collaborative effort between the Quality and Organ Recovery teams, leading to a clearly defined process.
- The verification form has been revised to be a meaningful and useful tool in the labeling and packaging process.
- This development process exposed the LOPA QI team to several new QI tools and more efficient ways to work.
- More organized, regular meetings would have allowed the process to progress more proficiently as the team would occasionally lose focus.
- Looking back, it would have been beneficial to include more clinical staff in the development process.