

Cover Page

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Title of Application: Ensuring System Wide Best Practices for Pre-cleaning and Transportation of Endoscopes

Topical areas of focus: Patient Safety and Quality Improvement

Brief Statement by an Executive Leader in Support of the Application: Submitted by Douglas Merrill, MD, MBA, Chief Medical Officer

I fully support the submission of the “Ensuring System Wide Best Practices for Pre-cleaning and Transportation of Endoscopes” project for the Hospital Quality Institute Vanguard Award. This project represents significant achievements in cultivating commitment, system engineering/design, implementing culture of safety and establishing infrastructure. Nationally, reports of deaths and outbreaks related to contaminated endoscopes have recently garnered much media attention. At the root of these issues has been the failure to adequately reprocess endoscopes and accessories, placing patients at risk for exposure to various pathogens. In preparation for accreditation visits by Joint Commission, we discovered that, despite high compliance with endoscope cleaning at UC Irvine Health, different approaches to pre-cleaning and transportation existed in different clinical areas, placing the organization at risk for quality and safety issues, as well as regulatory non-compliance. The Chief Operating Officer and I chartered a multidisciplinary team to implement standardization and best practices while eliminating waste and unnecessary complexity. Using Lean Six Sigma methodology, the team worked with front line staff to redesign those procedures. The project also achieved its fiscal goals of minimizing costs and remaining FTE neutral. One very impressive outcome of this work was the ability of the team to quickly cultivate a commitment to quality and culture of safety through shared leadership and accountability. Ultimately, the effort was successfully implemented within a six-week period as evidenced no findings related to pre-cleaning and transportation of endoscopes during our triennial Joint Commission reaccreditation survey.

Executive Summary

Preparation for our Joint Commission (TJC) re-accreditation survey revealed that, despite centralizing endoscope cleaning at UC Irvine Health, different approaches to pre-cleaning and transportation existed in clinical areas, placing the organization at risk for quality and safety issues, as well as regulatory non-compliance. Executive Leadership chartered a multidisciplinary Disappearing Task Force (DTF) to implement standardization and best practices while eliminating waste and unnecessary complexity. Using Lean Six Sigma methodology, the team quantified significant variability in the techniques related to precleaning and transportation of endoscopes, then worked with front line staff to redesign those processes. To ensure patient safety within the clinical processes/systems of care, a standardized approach precleaning and transportation was implemented across the organization. Important to sustainability were establishing workflow appropriate to the various environments (inpatient, outpatient, onsite, off-site), employing visual cues for clean/dirty items (green/red, respectively) and implementing custom-made precleaning kits to drive process. The project also achieved its fiscal goals of minimizing costs and remaining FTE neutral. The effort was implemented as a Rapid Cycle effort (6 weeks from initiation to house-wide implementation). Successful implementation was measured during the TJC survey approximately 60 days later. The organization had no findings related to pre-cleaning and transportation of endoscopes.

Application

Ensuring System Wide Best Practices for Pre-cleaning and Transportation of Endoscopes

3. Background: Reports of deaths and outbreaks related to contaminated endoscopes have recently garnered much media attention. At the root of these issues has been the failure to reprocess or to inadequately reprocess endoscopes and accessories, placing patients at risk for exposure to various pathogens. To ensure quality and safety during the reprocessing of endoscopes, UC Irvine Health consolidated high level disinfection (HLD) activities to three primary locations in 2013. This early adoption of centralization resulted in many improvements related to the quality and safety of endoscope reprocessing. However, recent assessments by our internal infection prevention and accreditation teams revealed that, despite the centralization efforts, different approaches to pre-cleaning and transportation of endoscopes existed, placing the organization at risk for quality and safety issues, as well as regulatory non-compliance. In response to these findings, the Executive Leadership team chartered a multidisciplinary Disappearing Task Force (DTF) focused on system redesign which would result in standardization and best practices for the pre-cleaning and transportation of endoscopes while remaining FTE neutral and eliminating waste (MUDA)/unnecessary complexity. The DTF embarked on a house-wide rapid cycle implementation of best practices for pre-cleaning and transportation of endoscopes.

4. Describe the Effort: The multi-disciplinary DTF was led by a Lean Six Sigma Black Belt and included members from Regulatory Affairs, Infection Prevention, and the Sterile Processing Department (SPD), as well as staff representing all area using endoscopes including the ENT Clinic, the Chao Digestive Disease Center (CDDC aka GI Endoscopy Lab), Urology Clinic, Emergency Department, Operating Room, Respiratory Therapy and Inpatient Nursing. The team used Lean Six Sigma methodology to address system engineering and design with the goal of establishing current practices, identifying challenges, and implementing an organization-wide standard for pre-cleaning and transportation of endoscopes.

The Define-Measure-Analyze phases of the project were implemented using various lean Six Sigma methodologies. Process mapping revealed a high level of variability across the organization with eight (8) distinct approaches to pre-cleaning, six (6) different transport containers and inconsistency in precleaning supplies (pre-made kits vs. kits made by Sterile Processing Department vs. individually purchased supplies). Investigations into the root causes of the variability revealed that organizational pressure to address quality, safety and regulatory issues quickly and a lack of a single source of definitive information led to solving issues in silos. The Voice of the Customer discussion also elucidated primary stakeholder concerns regarding standardization including costs, time/workflow, waste, availability of supplies, space allocation, and possible regulatory non-compliance related to changing processes. Using a risk: benefit approach (figure A), the team evaluated various solutions including process currently implemented successfully within the organization.

The cost analysis portion of the risk: benefit analysis created transparency related to costs and waste, yet concerns regarding time/workflow, and space allocation still remained. To help overcome resistance in these areas, the DTF conducted a Gemba walk using sample products,

which included hands on assessment by front line staff to ensure that workflow was manageable at the from their perspective. Finally, a regulatory analysis using CMS, Joint Commission, Association of periOperative Registered Nurses (AORN) and Association for the Advancement of Medical Instrumentation (AAMI) as well as literature from the various professional societies was conducted on the proposed changes to ensure that all aspects of quality, safety and compliance were met.

5. Results: Process mapping elucidated best practices for endoscope transportation had been implemented in the CDDC. This included the use of covered, neutral colored, puncture proof containers (known by the organization as “grey bins”, figure B) with disposable red and green covers for dirty and clean, respectively. This solution met the regulatory criteria for covered, puncture proof containers and the designation of clean from dirty. The cost analysis demonstrated that the CDDC was responsible for approximately 60% of the 2015 annual endoscope reprocessing volume. Therefore, the bottom line expenditures for changes to the transportation process could be reduced by employing their strategy and sunk costs for that area would be eliminated. Based on the sum of the learning from the Define-Measure-Analyze efforts, the DTF agreed that the methodology implemented in the CDDC should be implemented organization-wide.

The Gemba walk and voice of the customer events demonstrated that widespread implementation of the CDDC’s approach to transportation was feasible. However, implementation was not without challenges. The “grey bins” are slightly larger than some of the bins that we in use which created concerns regarding storage space. These concerns were overcome by purchasing the associated rolling carts in banks of six (6) or 10, depending on volume by location. In addition to a reducing the foot print for storage vs. counter space or cabinet space, the rolling carts created additional advantages including:

- A designated location for short-term storage of pre-cleaned or dirty endoscopes
- A method to ensure contained, wheeled (ergonomically correct) transportation of clean or dirty endoscopes from the onsite point of use to onsite SPD.
- A means for safe and compliant transportation of clean and dirty between the off-site point of use locations and the onsite SPD by installing the locking door version of the transport cart in the transport vans.

Standardizing the pre-cleaning process and supplies was inherently linked and thus solved simultaneously. Again the organization found best practices in the CDDC where pre-made pre-cleaning kits had already been implemented. The information from Define-Measure-Analyze phase demonstrated that the reprocessing volume for non-CCDC scopes was even split at 55% channeled and 45% non-channeled, whereas nearly 100% of the scopes in the CDDC were channeled. The organization also learned that the various kits/stand-alone supplies did not support best practices for pre-cleaning. The cost analysis revealed several important considerations:

- Savings could be realized by flushing first with water or saline vs all flushes with enzyme cleaner; an acceptable practice
- The organization could realize a 28.5% reduction in supply costs in the CDDC by switching vendors and converting to a standardized kit that could be used organization-wide.

- Further savings could be realized by standardizing to two (2) kits, one for channeled endoscopes and a second for non-channeled endoscopes as several items are not needed for the cleaning of the non-channeled equipment.
- The cost of disposing of small non-essential items not needed in all areas (e.g. 2 oz lubricating jelly) was negligible vs the cost savings for the standardized kits.

Based on the information from Define-Measure-Analyze phase, the DTF agreed that implementing two kits from a single vendor and centralizing stock to the Medical Center's warehouse was the ideal solution for organization-wide implementation. In addition savings directly related to the cost of the kits, centralizing supplies to the warehouse allowed the organization to establish actual par values for each type of kit and rotate stock (FIFO) to highest users, potentially resulting in additional saving.

6. Significance of the Results: Through shared leadership and accountability for system redesign, cost control and a team commitment to eliminating unnecessary complexity, quality, safety, staff satisfaction and regulatory compliance were all improved. The use of standardized transport containers with red-green covers provides visual cues for safety for all staff, not just those involved in the endoscopy process, and allows for quick observations of compliance during compliance rounds/tracers. The simplicity of the solution also allows for compliance assessment by non-clinical management. Recent feedback from staff demonstrates a high level of approval with standardized transport process and an appreciation for the clarity of the organization wide approach. An unexpected positive impact from implementation of the grey bins and wheeled carts was the ability to free up space in utility rooms. Because the grey bins don't carry the stigma of dirty associated with the traditional red biohazard bins, storage of clean bins with green covers (visual cue) were readily accepted in the clean utility rooms. Areas with high volume opted for wheeled carts in both the clean and dirty utility rooms, which reduced the amount of counter space/footprint needed for storage and provided greater protection vs stacking one bin on top of the other. For areas not using the wheeled carts, the bins easily stack inside each other on shelves vs the traditional red bins which needed to be stacked on top of each other.

The alignment of supplies to the pre-cleaning process created significant improvements in workflow, as well as obvious benefits to patient care, quality and safety. Again, the post-implementation feedback from staff demonstrates a high level of satisfaction with the simplicity and standardization of the precleaning process and the ease of implementation regardless of location.

While an initial investment was required for the transport containers and carts, cost savings was achieved through the purchase of standardized pre-cleaning kits. The project remained FTE neutral. In the long-term, further saving may be realized since the protection offered by the grey bins and wheeled carts may provide a reduction in the number of scopes damage during transport to SPD.

Remarkably, the DTF was able to tackle the system-wide project as a rapid cycle improvement effort, completing its charge in approximately 6 weeks from analysis to implementation and including an internally developed training video on the new pre-cleaning process. Notably, the organization underwent their triennial Joint Commission reaccreditation survey approximately 60 days after implementation and had no findings related to pre-cleaning and transportation of

endoscopes. While survey results represent only an early indicator of successful implementation, they point to a high likelihood of sustainability.

7. Sustainability and Scaling: The project was chartered with the goal of organization-wide implementation. Nonetheless, influences on scaling and sustainability were present. The major impact on both criteria was the endoscopy volume in the CDDC. Since approximately 60% of the endoscopy volume is generated from this location, solutions needed to compliment workflow in this area to ensure sustainability. Project bottom line, a key component of sustainability, was also heavily influenced by the CDDC volume. A secondary sway on scaling and sustainability worked in the organizations favor. Notwithstanding bedside bronchoscopy, other endoscopy procedures were primarily limited to designated service lines and specific locations (e.g. urology, ENT). This phenomenon allowed the DTF to leverage intangibles such as culture of safety and personal accountability to engage the DTF members in reducing costs and ensuring new processes did not create unnecessary complexity, key factors to sustainability. The DTF was also able to leverage this trend to ensure a smooth transition from concept to practice and a simultaneous system-wide roll-out.

Other factors contributing to successful sustainability included:

- Involvement of the respiratory therapists to determine pre-cleaning workflow in the inpatient setting
- Selecting products in the customized pre-cleaning kit that are available from multiple vendors, thereby creating negotiating power for best prices
- Centralizing product availability to the Medical Center warehouse to ensure appropriate par values and prevent waste secondary to expired contents
- Grey bins are re-useable bins easily cleaned with surface disinfectant
- Redesigned workflow that fits all scenarios (on-site, off-site, inpatient, ambulatory)

8. Lessons Learned: Shared leadership and accountability for system engineering and redesign can effectively produce rapid cycle change that can be scaled for organization wide implementation. Conversely, improving systems in silos create opportunities for error, regulatory non-compliance and can result in less than optimal use of fiscal resources. Challenges to personal preferences when addressing major system changes can best be overcome through transparency regarding concerns and data, inclusion of front line staff and use of proven performance improvement methodologies such as Lean Six Sigma. Culture of safety and sustainability are also positively impacted when front line staff are engaged in the system engineering and design.