Improving Patient Safety for our Nation's Veterans: Reducing Risk and Increasing Quality of Care by Implementing an Automated Quality Management System within Sterile Processing Operations

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Objective: Enhance patient care for our nation's veterans by reducing risk, improving patient safety, and increasing quality of Sterile Processing Services (SPS) operations for the New York/New Jersey VA Health Care Network, consisting of 10 VA Medical Centers and 59 outpatient clinics.

Planning/Research Methods: The VA Health Care Network aligned governance for SPS operations through the creation of an ISO 9001 Quality Management System (QMS) for Sterile Processing Services. The QMS encompasses all SPS departments within the Network and initiated the journey to ISO 9001 certification for all VISN 2 Medical Centers. The Network Quality Management Office created multi-disciplinary quality assurance teams to examine and review existing SPS processes and procedures across core functional areas based on key principles of the ISO 9001 Standard: Organizational Context; Leadership, Governance and Support; SPS Infrastructure Requirements; SPS Operational Requirements; Program Evaluation; and Continuous Quality Improvement. The analysis also considered program complexity, human and capital resources, compliance with program and regulatory requirements, and other core safety functions.

Implementation Methods: The multi-disciplinary teams developed six standard operating procedures (SOPs) with corresponding protocols that detail the reprocessing instructions for critical and semi-critical reusable medical devices (RMD) and eliminated the need to track 1,000s of paper records. These SOPs were organized around designated operational areas within SPS: Intake, Decontamination, Preparation and Assembly, Sterilization, Sterile Storage, and Outtake and Delivery. The teams applied LEAN principles to also implement protocols and policies for the program management and oversight of high-risk devices at the Network level. An Electronic Quality Management System (eQMS) was developed to serve as the data repository and is also used for tracking and validating the standardized protocols and policies, reusable medical devices, and procedural kits used across the Network. The eQMS platform provides at-a-glance, step-by-step reprocessing guidance to each SPS staff member at their workstations. The immediate access to knowledge and resources for SPS staff has been critical to increased patient safety and reducing risk. The tools within the eQMS were disseminated through trainings, hotlines, and readiness assessments to ensure uniformity, and progress was tracked using a gamification strategy. The eQMS also serves as a Quality Monitoring tool utilizing dashboards to track and trend required quality metrics for continual quality improvement. Additionally, a Customer Portal on the eQMS allows clinical staff to provide real-time feedback to the SPS department as needed.

Results: Patient Safety and Quality Improvement was the driving force for implementing ISO 9001 within Sterile Processing Services. The VISN 2 Network successfully received and maintains certification in SPS and holds 1 of 30 ISO 9001:2015 certifications in the U.S. Health and Social Work sector. The eQMS system has been implemented across the Network and allows the Network to take a proactive and collaborative approach to risk reduction, continuous process improvement, and has resulted in enhanced patient care for our nation's veterans. Areas of improvement include:

1. **RMD Cancelled Surgeries:** From 2018 to 2023 RMD-related Surgical Cancellations have dropped below 1 cancellation per VAMC per quarter, resulting in a greater than 70% decrease
2. **Joint Commission Findings Related to SPS:** No "Requirements for Improvement" for Sterile Processing Services during the last triennial surveys across the Network
3. **ISO 9001:2015 Certification Audit Findings**: Few to no findings identified during ISO 9001:2015 Certification Audits
4. **RMD Inventory Loss**: Significant reduction in shrinkage for RMD across the Network
5. **Customer Satisfaction:** Positive Customer feedback increased by more than 40% from 2018 to 2023 and verified corrective actions have been taken for greater than 80% of all customer complaints during the same time period
6. **Standardized Processes:** Area SOPs detail the reprocessing instructions for approximately 80% of critical and semi-critical reusable medical devices (RMD), condensing 1,000s of paper records into six digital protocols
7. **Automated Data Collection and Reporting:** Automatically collect and visualize 35+ indicators in dynamic dashboards
8. **Automated Electronic Display of Protocol Instructions:** Automatically link to and visualize 441 protocols and cleaning instructions for individual RMD