Endoscope Reprocessing:
A Failure Modes & Effects Analysis & Improvement Collaborative

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During Quality Review at the end of a busy day in our Scope Reprocessing Workroom, it was discovered that the colonoscope used on Patient B had correctly been entered into the daily logbook but was missing in the Medivator® data history confirming it had been reprocessed.

We greatly feared that the scope used on Patient B had not undergone HLD after use on Patient A.

A deep dive ensued and final investigation revealed that the scope used on Patient A had actually had the paperwork scanned twice, while that of Patient B had not been scanned at all. Findings proved that a documentation error vs. a reprocessing error had occurred.

A Risk Management investigation was initiated to address this patient safety concern.

Investigative Findings

- **Opportunities for applying Risk Management principles:**

  -Roles not well defined – no segregation of responsibilities
  - QC method in place retrospective (only done at end of shift)
  - No assigned RN oversight of the process

- **Opportunities to apply lean principles to a detailed yet repetitive process:**

  -Evaluate workflow and necessary steps
  -Standardize the work
  -Increase the use of electronic data entry to reduce manual/error-prone documentation
  -Maximize staff productivity

- **Opportunities to capitalize on Medivators Advantage Plus® functionality**

Goals

1. **Validate our confidence in the accuracy/completeness of our unit's scope reprocessing workflow**
2. **Reduce risk of error in linking scope-to-patient ID prior to reprocessing**
3. **Develop a QC real-time process to address encountered errors.**
4. **Assure compliance with SGNA™ Standards**

SGNA™
Society of Gastroenterology Nurses and Associates, Inc.

The “Scope” of our Unit

- **Number of scopes/day used in Endoscopy 45-60**
- **Number of scopes/day used outside of Endoscopy 8-10**
  (ASC, CV, CCU, OR, ST)
- **Reprocessors: Medivators Advantage Plus® 3 machines / 6 bays**
- **Hours of Operation: 6:30 am – 5:30 pm M-F plus 24-hour emergency coverage**
- **Staff/FTE:**
  RNs: 19 / 14.6
  Endo Technicians: 10 / 9.2

Failure Modes & Effects Analysis (FMEA) "Refresher"

- **Proactive risk assessment of a care or service process**
- **Identify steps in the process**
- **Identify failure modes (what could go wrong) for each step**
- **Assign risk number for Severity (S), Occurrence (O), & Detectability (D) for each failure mode**

  S x O x D = Risk Priority Number (RPN)

- **Rank RPN in descending order**
- **Develop action plans to mitigate/reduce highest risk steps**

FMEA Initial Analysis

Step	Failure Modes	Frequency	Severity	Detection	RPN
Pre-Procedure Prep	9	2	2	4	16
Initial Pre-Cleaning	7	10	2	4	80
*Washing/Leak-Testing	9	4	5	10	200*
*Loading into Reprocessor / High Level Disinfection	13	10	10	10	1000*
*Unloading, Rapicide Testing, QC	7	10	10	10	1000*
Drying, Tagging, Re-stocking	5	6	1	4	24

Frequency x Severity x Detection = RPN(Risk Priority number)

Highest Risk Steps = 3

Step	Failure Modes	Frequency	Severity	Detection	RPN
*Washing/Leak-Testing	9	4	5	10	200*

- Deliberate, redundant process
- Staff effectiveness fades over course of shift
- Complicated & detailed work –

  especially with multi-channel and

  specialty scopes

Step	Failure Modes	Frequency	Severity	Detection	RPN
*Loading into Reprocessor / High Level Disinfection	13	10	10	10	1000*

- No role delineation
- Error-prone documentation
- Scanning discrepancies
- Frequent, unplanned downtimes causing disruptions in workflow and distractions

Step	Failure Modes	Frequency	Severity	Detection	RPN
*Unloading, Rapicide Testing, QC	7	10	10	10	1000*

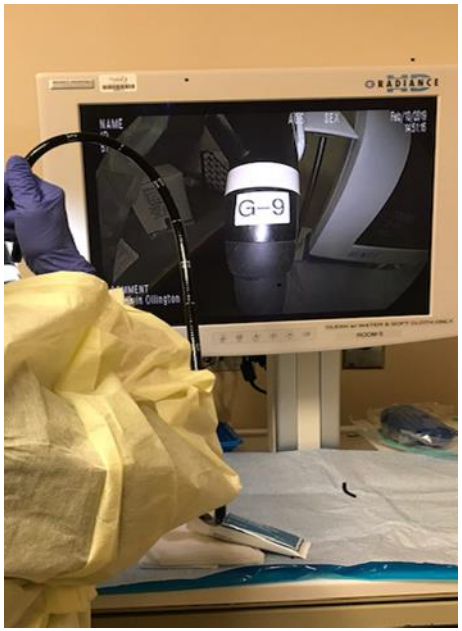
- Redundant, error-prone manual documentation
- Inconsistent, retrospective QC plan done at the end of the day
- QC sample size not reflective of workload or risk profile

Action Plan

- **Dedicated Washing role**
  -Rotated at mid-day to prevent staff fatigue and maintain maximum effectiveness.
- **Separation of Loading & Unloading roles**
  -Loader role expanded to include choosing random scopes to undergo ATP testing
- **Addition of QC RN/Tech role**
  -Tests Rapicide & performs QC in real-time - *before* scope is removed from the reprocessor -
  - In charge of unloading scope, drying and yellow-tagging.
- **General RN oversight of daily process**
  - If a discrepancy is found, an immediate "Time Out" is called; the designated RN &/or NM is notified; all tasks are suspended until the issue is resolved.
- **Revision of Electronic Documentation**
  -Washer (role added to Medivators electronic documentation)
  -Loader -Unloader/Rapicide Tester/QC

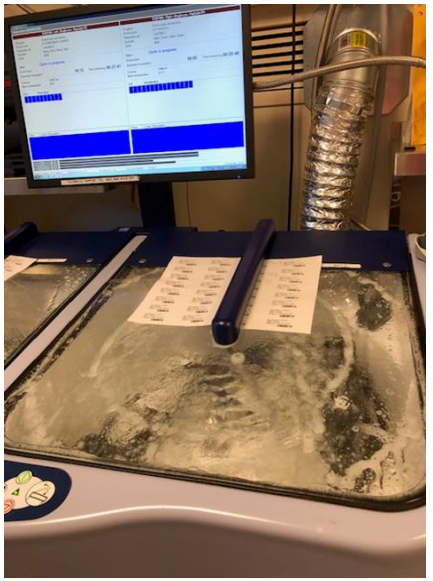
Additional Action Plan Items

- **Revision of Intra-procedure Universal Protocol process to include verbalization of scope ID number & presence of yellow tag, which signifies that all reprocessing steps were completed.**



- **Picture of the Scope ID taken at start of case and included as part of the patient's EMR**

- **Placement of patient's barcode sheet on designated Medivator bay throughout reprocessing cycle for scope ID verification**



- **Bar code scanning done away from the reprocessor to prevent scanning errors**

- **Revision of Scope Workroom logbook to eliminate/reduce manual entries**

- **Addition of Workroom Communication Book for documentation of encountered trends and issues – staff are expected to check the book daily.**
- **Specimen drop-off/pick-up relocated to decrease washer distractions**
- **Electronic QC done at the end of *each* cycle, utilizing patient bar code sheet.**
- **QC checks include: Patient MR #, physician name, scope ID, designated staff roles in reprocessing cycle and assurance that all parameters of cycle "passed."**

Did Our Action Plan Make a Difference?

Step	Failure Modes	Frequency	Severity	Detection	RPN
Washing/Leak-Testing	9	4	5	10	200
REVISED	9	3	5	4	60
Loading into Reprocessor/ HighLevel Disinfection	13	10	10	10	1000
REVISED	10	2	10	4	80
Unloading, Rapicide Testing, QC	7	10	10	10	1000
REVISED	5	6	1	4	24

Absolutely!!!

Members of the BH/AGH Endoscopy Team