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

Linda Allen RN
Jeanetta Kumar RN
Cheryl Thomas-Shackleton BSN, RN
Barbara McCarthy RN, MPH, CIC, CPHQ,
CPHRM, FASHRM
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
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
  \[ S \times O \times D = \text{Risk Priority Number (RPN)} \]
- Rank RPN in descending order
- Develop action plans to mitigate/reduce highest risk steps
## FMEA Initial Analysis

<table>
<thead>
<tr>
<th>Step</th>
<th>Failure Modes</th>
<th>Frequency</th>
<th>Severity</th>
<th>Detection</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Procedurpe Prep</td>
<td>9</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Initial Pre-Cleaning</td>
<td>7</td>
<td>10</td>
<td>2</td>
<td>4</td>
<td>80</td>
</tr>
<tr>
<td>*Washing/Leak-Testing</td>
<td>9</td>
<td>4</td>
<td>5</td>
<td>10</td>
<td>200*</td>
</tr>
<tr>
<td>*Loading into Reprocessor / High Level Disinfection</td>
<td>13</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>1000*</td>
</tr>
<tr>
<td>*Unloading, Rapicide Testing, QC</td>
<td>7</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>1000*</td>
</tr>
<tr>
<td>Drying, Tagging, Re-stocking</td>
<td>5</td>
<td>6</td>
<td>1</td>
<td>4</td>
<td>24</td>
</tr>
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\[
\text{Frequency} \times \text{Severity} \times \text{Detection} = \text{RPN (Risk Priority number)}
\]
### Highest Risk Steps = 3

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- Deliberate, redundant process
- Staff effectiveness fades over course of shift
- Complicated & detailed work – especially with multi-channel and specialty scopes
- No role delineation
- Error-prone documentation
- Scanning discrepancies
- Frequent, unplanned downtimes causing disruptions in workflow and distractions

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Beverly Hospital
A member of Lahey Health
- 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

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**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?

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Absolutely!!!
Members of the BH/AGH Endoscopy Team

![Image of the BH/AGH Endoscopy Team]