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ABSTRACT

The main cause of endoscopy-associated infections is failure to adhere to reprocessing guidelines. More information about factors impacting compliance is needed to support the development of effective interventions. The purpose of this multisite, observational study was to evaluate reprocessing practices, employee perceptions, and occupational health issues. Data were collected utilizing interviews, surveys, and direct observation. Written reprocessing policies and procedures were in place at all five sites, and employees affirmed the importance of most recommended steps. Nevertheless, observers documented guideline adherence, with only 1.4% of endoscopes reprocessed using manual cleaning methods with automated high-level disinfection versus 75.4% of those reprocessed using an automated endoscope cleaner and reprocessor. The majority reported health problems (i.e., pain, decreased flexibility, numbness, or tingling). Physical discomfort was associated with time spent reprocessing ($p = .041$). Discomfort diminished after installation of automated endoscope cleaners and reprocessors ($p = .001$). Enhanced training and accountability, combined with increased automation, may ensure guideline adherence and patient safety while improving employee satisfaction and health.

Infection control has recently received a considerable amount of attention. Each year, there are more than 2 million healthcare-associated infections causing 90,000 deaths in the United States (Cockshut-Miller, 2004). Gastrointestinal (GI) endoscopes are used in more than 10 million procedures annually (Rutala & Weber, 2004), and contaminated endoscopes have been linked to more outbreaks of healthcare-associated infections than any other medical device (Rutala, Weber, & Healthcare Infection Control Practices Advisory Committee, 2008). Recent endoscope reprocessing problems have increased awareness of reprocessing challenges and shortcomings (Daigh, 2009; Stearns, 2009).

To prevent infections, several organizations have published endoscope reprocessing guidelines (Association of Operating Room Nurses, 1998; Nelson et al., 2003; Rutala et al., 2008; Society of Gastroenterology Nurses and Associates, Inc. [SGNA], 2010). Audits have shown that healthcare workers neglect to follow reprocessing guidelines, and the main cause of endoscopy-associated infections is failure to adhere to recommended protocols (Cowen, 2001; Nelson, 2005; Nelson et al., 2003; Rutala & Weber, 2004).

Automation can standardize processes and eliminate human shortcomings (Martiny, Floss, & Zuhlsdorf, 2004; Zuhlsdorf, Emmrich, Floss, & Martiny, 2002). According to the Centers for Disease Control and Prevention (CDC), "automated endoscope reprocessors (AER) offer several advantages over manual reprocessing: they automate and standardize several important reprocessing steps, reduce the likelihood that an essential reprocessing step will be

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skipped, and reduce personnel exposure to high-level disinfectants or chemical sterilants" (Rutala et al., 2008, p. 15).

Prior to this study, no data had been available regarding the routine clinical use of a new endoscope cleaning and reprocessing (ECR) machine, which standardizes cleaning and high-level disinfection (HLD) processes, eliminates brushing, performs alcohol flushing and forced air drying, and keeps complete records for each endoscope (Food and Drug Administration [FDA], 2005, 2006, 2008). The main purpose of this study was to evaluate the practices used to reprocess endoscopes, employee perceptions about reprocessing methods, and occupational health in settings using ECR and/or manual cleaning with HLD (MHLD) methods.

Methods

This prospective, multisite, observational study was conducted from October 2008 through April 2009. Sites were recruited from diverse geographic regions in the United States, and all were utilizing some type of automation to reprocess endoscopes. Data were collected via interviews, surveys, and direct observation, which is considered the "gold standard" method for evaluating healthcare worker adherence to infection control guidelines (The Joint Commission [TJC], 2009).

Research Personnel and Training at the Sites

Each site identified a site coordinator (SC) to manage study activities within its institution. The SCs were registered nurses (RNs) or endoscopy center managers with primary responsibility for overseeing the reprocessing facility and related activities. To ensure consistency, a single observer was appointed at each site to document actual practices used during endoscope reprocessing for the duration of the study. In accordance with TJC recommendations, observers were healthcare workers who did not work in the reprocessing area and were not managers or supervisors (e.g., a respiratory therapist). The research team provided training for observers regarding research methods, scientific documentation, and activities frequently performed during endoscope reprocessing. Observers were given a tour by the SC, who explained endoscope components and described the facility's reprocessing methods.

Data Collection Instruments and Protocols

Instrument design was based on scientific literature and discussions with managers and reprocessing personnel from several institutions. Surveys and log sheets were pilot-tested and refined prior to use. Researchers interviewed infection control and endoscopy center managers. Site coordinators completed a survey about institutional variables. Front-line reprocessing personnel completed surveys about reprocessing tasks, procedural delays and associated pressures, satisfaction, and occupational health issues at study initiation ("baseline") and 4-6 weeks after ECR installation or after baseline MHLD data were collected ("follow-up"). They also completed a survey about the ECR 1 week after installation. Surveys were returned directly to the research team.

Observers used a structured log sheet and stopwatch to document reprocessing practices for 15 endoscopes at baseline and 15 endoscopes at follow-up. Observation sessions occurred during 2-hour time periods over 4 or 5 days at baseline and at follow-up and were scheduled during normal business hours. Each observer remained in the reprocessing room from the time that a dirty endoscope was delivered until reprocessing was completed and the endoscope was hung up or available for use with another patient. The observer did not document any activities that occurred in patient care areas before the endoscope was delivered to the reprocessing area (e.g., bedside precleaning).

Each site approved the study protocol, and reprocessing personnel gave informed consent prior to survey completion. No experimental treatments or devices were used, and no patient data were collected. Prior to analysis, survey and log sheet data were aggregated and site identifiers were blinded.

Statistical Analyses

Compliance with endoscope reprocessing guidelines was defined on the basis of completion of 12 steps recommended by the SGNA, CDC, and Multi-Society Guidelines (Nelson et al., 2003; Rutala et al., 2008; SGNA, 2010). Personnel were responsible for performing each of the tasks listed in Table 1 (MHLD) or Table 2 (ECR). A completed ECR cycle included a leak test, channel and component cleaning, detergent immersion and flush, water rinse, air purge, HLD cycle, alcohol flush, and forced air drying (FDA, 2005, 2006, 2008). Personnel were responsible for the final exterior wipe-down following ECR.

Data were entered into Microsoft Office Excel 2007 spreadsheets using a double data entry methodology. SPSS (Version 14.0) for Windows was used for analyses. The analysis utilized frequency distributions and contingency tables initially broken down by type of reprocessing method (MHLD or ECR) and data collection period. Differences were tested using Fisher's exact test and the chi-square test for trends, when appropriate. When differences between

TABLE 1. Observed Steps for Manual Cleaning With High-Level Disinfection Reprocessing

Leak testing
Disassembling scope
Brushing
Using detergent
Rinsing with water
Purging with air
Running AER cycle
Flushing with alcohol
Using forced air to dry
Removing from AER and wiping down

Note. AER = automatic endoscopic reprocessing.

groups were not statistically significant, results were combined.

Results

Site Characteristics and Response Rates

Six sites were recruited for participation in the study, and five submitted complete data sets. The sixth site did not complete data collection because of unanticipated personnel changes that occurred shortly after study initiation. Sites included two gastroenterology specialty centers, two multispecialty hospitals, and one outpatient surgery center. Survey response rates were very high, with more than 87% of expected surveys completed.

TABLE 2. Observed Steps for ECR Machine Use

Disassembling scope
Attaching all connectors
Entering data using touch screen
Ensuring reservoirs are adequately filled
Running ECR cycle (including leak test, channel and component cleaning, detergent immersion and flush, water rinse, air purge, high-level disinfection cycle, alcohol flush, forced air drying)
Verifying cycle completion (or restarting after addressing reasons for cycle failure)
Removing from ECR and wiping down

Note. ECR = endoscopic cleaning and reprocessing.

The data set included 36 baseline, 34 follow-up, and 23 one-week surveys. Observers submitted 99% of expected log sheets. Data on 183 GI endoscopes were analyzed.

All managers affirmed that their facilities had written reprocessing policies and procedures. Four were based on the SGNA guideline, one was based on the SGNA and American Society of Gastrointestinal Endoscopy (ASGE) guidelines (ASGE Standards of Practice Committee, 2008), and one site had developed its own internal policies.

The average number of endoscopy procedures varied by site (from 10 per week to 250 per week). Managers indicated that their institutions used one or more types of automation for reprocessing. At baseline, three sites utilized mechanical irrigators (Medivators Scope Buddy), three used AERs from Advanced Sterilization Products (ASP), one used a Steris System 1 Sterile Processing System, and two used ASP's Evotech ECR. New Evotech systems were installed at four sites, whereas one site used only MHLD for the duration of the study.

Employee Characteristics

Sites employed between 4 and 13 persons who were trained to reprocess endoscopes, including scope technicians or medical equipment specialists (26%), RNs (50%), and others (24%). Observers documented that 24% of reprocessing was performed by RNs during this study. Three fourths of respondents had reprocessed endoscopes for more than 1 year, and approximately 40% had done so for 5 years or more. One-half reported working 8 hours or less per week reprocessing endoscopes, whereas 20% spent 25 hours or more per week on this task. Reprocessing personnel also performed other duties at four sites. The fifth site had staff devoted entirely to reprocessing.

Employee Perceptions About Reprocessing Tasks

More than 90% of survey respondents considered the leak test, brushing, and water rinse steps to be very important, and 79% believed air purging was very important. Most respondents (>90%) reported liking endoscope setup, patient care, and removing clean endoscopes from the HLD systems, and 87% liked loading the AER or the ECR machine. Less popular tasks were leak testing, bedside wipe-down, alcohol flush (each liked by approximately 60%), and manual cleaning (defined as brushing/flushing) before disinfection (47%).

The majority (65%) of personnel using MHLD methods stated that they typically spent 1-2 minutes brushing each endoscope. Longer brushing times were reported by 18% of respondents, and shorter times by 18%. When using MHLD, 12% of employees found leaks in the last month; 22% of employees using the ECR machine found leaks.

More than 97% of respondents rated their reprocessing systems as very easy or easy to use. The majority of personnel (>71%) described MHLD and ECR methods as excellent or very good. Differences between groups were not significant.

Occupational Health Issues

At the time of study initiation (baseline survey), the majority of employees reported health problems, which they attributed to reprocessing endoscopes (Figure 1). Symptoms included respiratory ailments related to fumes or odors in the reprocessing area (reported by 18% of respondents) and physical discomfort (reported by 50% of respondents). For those with physical discomfort, symptoms involved employees' backs or necks (91%), hips, legs, or feet (76%), and hands or arms (47%). The most common problems reported were pain (92%), problems with flexibility (36%), and numbness or tingling (30%) in one or more bodily region. At follow-up, health problems occurred less frequently among personnel using the new ECR machine than those using MHLD (p = .001).

At baseline, nearly one third of employees with occupational health problems believed the symptoms interfered with their ability to function inside and outside of work (Figure 2). Employees reported missing work because of these health problems (p = .000).

At baseline, there was a linear relationship between physical symptoms and the number of hours spent reprocessing each week (p = .041) (Figure 3). This association was not found at follow-up (p = .472).

Managers at three sites were aware that employees had experienced occupational health problems, and one reported that employees had current health problems associated with reprocessing endoscopes. Sites added floor cushions, removed and reattached sinks at a more appropriate height, rearranged schedules for shorter cleaning periods, and sent employees to physical therapy to address occupational health problems.

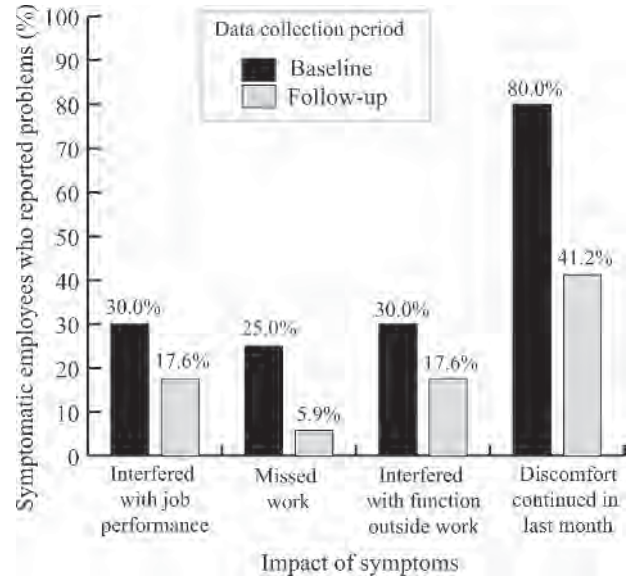

FIGURE 2. Impact of occupational health problems attributed to reprocessing endoscopes (p = .000).

Reprocessing Efficiency

Three fourths (75%) of employees reported feeling pressure to work quickly when reprocessing endoscopes. One respondent acknowledged skipping steps or doing them more quickly than they liked because of this pressure. Automated endoscope reprocessing cycle failures in the past week were reported by 10% of respondents. Endoscopic cleaning and reprocessing cycle failures were more common, with 52% of respondents reporting one to three cycle failures in the past week, and 21% reporting four or more. ECR

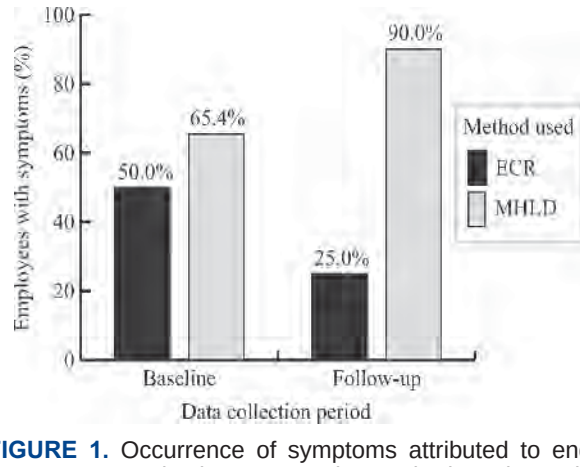

FIGURE 1. Occurrence of symptoms attributed to endoscope reprocessing by reprocessing method used over time (p =.001).

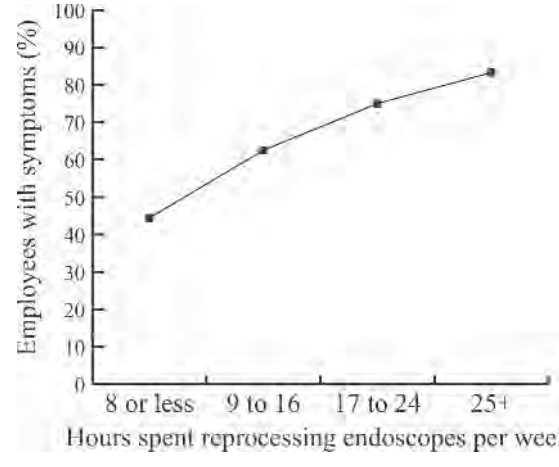

FIGURE 3. Association between the occurrence of physical discomfort attributed to reprocessing and hours spent reprocessing endoscopes per week at baseline (p = .041).

failures were generally due to user error (e.g., incomplete channel connections, failure to refill reservoirs). Approximately 46% of personnel reported procedural delays due to a lack of clean and disinfected endoscopes. There were no significant differences in the occurrence of procedural delays by method used (MHLD vs. ECR).

Observed Performance

Personnel performed all 12 required steps for 1 of 69 (1.4%) endoscopes reprocessed using MHLD, and for 86 of 114 (75.4%) endoscopes reprocessed using ECR. There were significant differences in the number of steps skipped by method (p = .000). Table 3 illustrates the completion of required steps for endoscopes reprocessed using MHLD. Less than half of endoscopes had all components brushed. Alcohol flush and forced-air drying steps were commonly skipped. Observers documented that 22% of wet leak tests performed prior to MHLD were performed using sudsy water. Figure 4 shows that personnel skipped two or more steps for 44.9% of MHLD-reprocessed endoscopes and for 0% of ECR-reprocessed endoscopes. The only step skipped for endoscopes reprocessed using ECR was the final wipe-down (25% skipped).

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

Observed Activity	Steps Completed (%) (n = 69)
Leak test performed in clear water	77
Disassemble endoscope completely	100
Brush all endoscope channels and components	43
Immerse endoscope completely in detergent	99
Immerse components completely in detergent	99
Flush endoscope with detergent	99
Rinse endoscope with water	96
Purge endoscope with air	84
Load and complete automated cycle for high-level disinfection	100
Flush endoscope with alcohol	86
Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

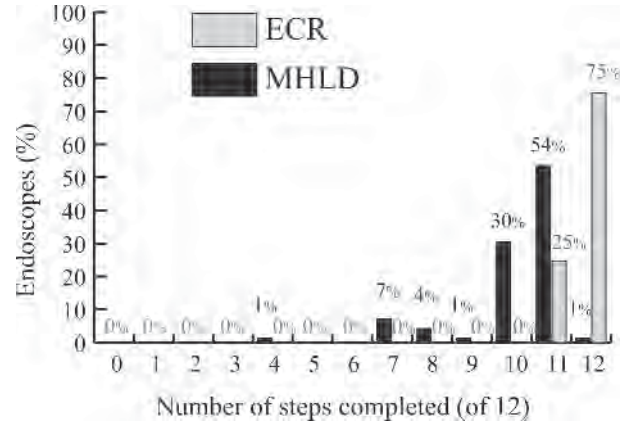

FIGURE 4. Personnel completion of endoscope reprocessing steps (p = .000).

Time spent brushing varied considerably (Figure 5a). Median brush time was 1 minute 12 seconds at baseline and 1 minute 34 seconds at follow-up (range from 10 seconds to 7 minutes 44 seconds). The site with the highest rate of documented brushing of all endoscope channels and components (Site B) had the longest brushing times. Brushing times at Site E (MHLD only) were shorter and decreased significantly from baseline to follow-up (mean value = 1 minute 10 seconds at baseline and 42 seconds at follow-up; p = .000). Personnel flushed endoscopes with detergent for a minimum of 18 seconds and a maximum of 2 minutes 45 seconds. Time spent rinsing with water ranged from 1 minute 17 seconds to 3 minutes 20 seconds (Figure 5b). Sites B and E used a mechanical channel irrigator with a programmed timer and had more consistent flush times than Site A.

Discussion

Safe endoscope reprocessing requires meticulous adherence to guidelines. Human error is a principal cause of deficient reprocessing (Alfa, Olson, & DeGagne, 2006; Nelson, 2005; Rutala & Weber, 2004). Guidelines may be valuable for detailing proper practices but can be ineffective for changing behavior (TJC, 2009).

This is the first study that evaluated reprocessing practices in clinical settings before and after the introduction of a new ECR method. Although managers affirmed that written reprocessing policies and procedures were in place and employees acknowledged the importance of reprocessing steps, direct observation revealed that GI endoscopes were generally not reprocessed in accordance with guidelines. We found that only 1 of 69 endoscopes was reprocessed properly when manual reprocessing methods were used. In spite

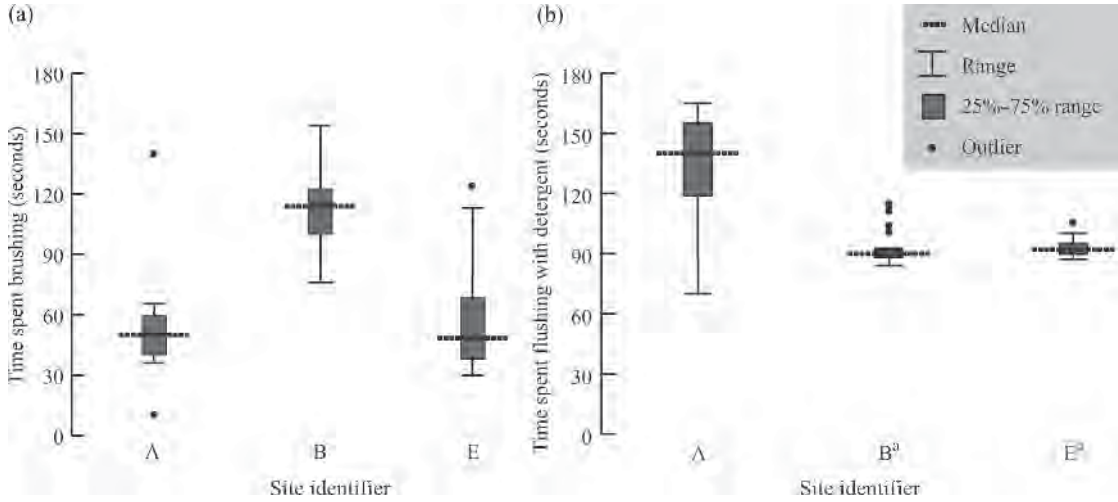

FIGURE 5. Observed cleaning times at manual high-level disinfection sites: (a) brushing durations; (b) flushing durations. [a]Sites B and E used an automated method with a timer.

of reprocessing inadequacies observed in this study, employees performed critical steps more consistently than reported by other researchers who found that 64% of endoscopes were correctly immersed in detergent, 68% were rinsed with water, and 89% were flushed with alcohol (Alfa, Olson, DeGagne, & Jackson, 2002). Jackson and Ball (as cited in Nelson et al., 2003) also found reprocessing deficiencies in every 1 of 19 primary care clinics that performed flexible sigmoidoscopies.

Nonadherence with reprocessing guidelines can have serious implications. Seoane-Vazquez, Rodriguez-Monguio, Visaria, and Carlson (2006) evaluated data related to 70 outbreaks of endoscopy-related infections and found that the primary cause was deficient reprocessing practices. They concluded that the improvement of quality control systems could have prevented 91% of the infections and suggested that surveillance systems be improved to reduce the burden of endoscopy-related events.

The leak-testing results were not surprising. Other researchers have reported one third of endoscope leaks are overlooked by personnel (Dix, 2007) and even seasoned technicians commonly miss leaks (Ellis, 2006). According to Ellis (2006), technicians sometimes "…combine the cleaning with the leak test and dunk the scope in a tub of enzymatic solution, so you're looking for bubbles within bubbles" ("Leak Testing," ¶ 10). The failure to perform a proper leak test could also have serious implications. Continuing to use a damaged endoscope could result in further damage and related expenses (Dix, 2008).

In this study, personnel brushed all components on less than 50% of endoscopes, and brushing times varied considerably. Some endoscopes received less than 30 seconds of brushing, and only 2 of 76 brush times were longer than 3 minutes. Others have suggested that proper manual cleaning takes substantially longer time than that found in this study (Alfa et al., 2006). The lack of meticulous brushing is problematic because improper cleaning "…can overwhelm the high-level disinfection process and result in a contaminated device regardless of subsequent steps" (Burdick, & Hambrick, 2004, p. 718). Observed brushing times were lower than indicated on surveys, which suggests that employee self-report of reprocessing practices was unreliable. The significant reduction in documented brushing times from baseline to follow-up at the MHLD-only site (p = .000) indicates the need for continuous monitoring, as any positive impact the observer may have had seems to have waned by the end of the study.

Others have reported that the automation of cleaning and HLD processes reduces the impact of human shortcomings and results in more consistent endoscope reprocessing (ASGE Standards of Practice Committee, 2008; Rutala et al., 2008; Zuhlsdorf et al., 2002). We found consistency improved when automated devices were used. The use of a Scope Buddy at two sites resulted in detergent flush times that were quite consistent. The use of an ECR machine further improved consistency, with 100% of endoscopes being leak-tested, cleaned, treated with HLD, and dried with alcohol and forced air. Even with ECR, however, employees sometimes skipped the final wipe-down.

User error was the most common cause of cycle failures. These errors were documented automatically and required employees to address the issues and restart the cycles. ECR documentation ensured that partially reprocessed endoscopes were not returned to circulation and allowed managers to identify problems with the technology and employee performance.

Our findings provide new information about the context in which guideline nonadherence occurs. First, reprocessing endoscopes involves a complicated series of steps, and a substantial proportion of employees indicated they disliked leak testing, manual cleaning, and flushing with alcohol. Observers documented that these tasks were often skipped or improperly performed. Although observers did not document bedside precleaning, survey data indicated that approximately 40% of employees do not like performing this step. Direct observation revealed that the final wipe-down was frequently skipped. The improper performance of bedside precleaning or the final wipe-down, whether MHLD or ECR methods are used, could have a negative impact on reprocessing effectiveness.

Second, the need to rapidly handle a high volume of endoscopes and prevent procedural delays may contribute to a stressful work environment (Dix, 2007; Hession, 2003). We found that most employees felt pressure to work quickly, and many attributed procedural delays to a lack of reprocessed endoscopes. According to Hession, "On a typical day, two rooms were delayed three times each, for a total of 1 hour of idle time due to instrument processing delay" (2003, p. 112). Procedural delays impact patient satisfaction and have financial implications (Hession, 2003).

Third, most employees experienced health problems, including respiratory problems, pain, tingling, numbness, and decreased flexibility, attributed to reprocessing endoscopes. Several workers indicated that the symptoms interfered with their job performance. At baseline, we found a linear association between hours worked and symptoms experienced. After four of the sites had begun to use the new ECR machine, significantly fewer workers reported discomfort attributed to reprocessing and the linear relationship between hours spent reprocessing and symptoms disappeared.

Study Limitations

Direct observation was used to document practices used for reprocessing endoscopes from a convenience sample (i.e., nonrandomized) of endoscopes. The SCs and observers scheduled observation times at their discretion, which could have impacted the findings. The presence of an observer may have affected employee behavior because of a "Hawthorne effect" (Kohli et al., 2009), potentially resulting in higher adherence levels than those that occur when employees are not being monitored. The findings may not be generalizable because they came from a small number of diverse sites that volunteered to participate. This was an open-label observational study, and personnel were aware of which reprocessing methods were being used, which could have affected the results. The implications of the observed variability in reprocessing practices are unknown because there was no laboratory confirmation of cleaning effectiveness, and no patient outcomes data were collected.

Conclusions

This multisite study documented extensive nonadherence with reprocessing guidelines when manual reprocessing methods were used. We identified a constellation of factors that may contribute to nonadherence, including employee dislike of manual reprocessing tasks, pressure to work quickly, and occupational health problems attributed to reprocessing. Automation resulted in better compliance with guidelines and reduced symptoms associated with reprocessing.

Enhanced training programs may improve performance of some tasks; however, these human factors are unlikely to be modified through education alone. Routine monitoring of reprocessing practices would allow management to identify and correct deficiencies. Ongoing audits and continuous vigilance may be required to ensure compliance with guidelines. Endoscopy center managers should also address time pressures and health problems experienced by employees. The use of ECRs may be helpful in this regard, as they have preset reprocessing cycle times, reduce the need for hands-on involvement by personnel, and provide documentation for all cycles. In addition, the use of more automated reprocessing methods will improve compliance with reprocessing guidelines that have been developed to ensure patient safety. ✪

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According to a recent study, the EVOTECH® Endoscope Cleaner and Reprocessor (ECR) automated cleaning is superior to traditional manual cleaning.[1] A study published in this journal also shows how the EVOTECH® ECR can improve productivity, worker safety and compliance.[2]

The studies demonstrate that the EVOTECH® ECR can:

- Provide effective removal of both organic material and bioburden from all channels and all surfaces of the flexible endoscopes evaluated.[1]
- Reduce occupational health symptoms by 65% compared to traditional reprocessing.[2]

For more study results, please visit www.aspjj.com.

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1 Alfa MJ, DeGagne P, Olson N, Fatima M. EVOTECH endoscope cleaner and reprocessor (ECR) simulated-use and clinical-use evaluation of cleaning efficacy. *BMC Infectious Diseases* 2010, 10:200 doi:10.1186/1471-2334-10-200.

2 Ofstead, C. L., Wetzler, H. P., Snyder, A. K., & Horton, R. A. (2010). Endoscope reprocessing methods: A prospective study on the impact of human factors and automation. *Gastroenterology Nursing*, 33(4), 304 -311.