



State of the Science Review

Challenges in achieving effective high-level disinfection in endoscope reprocessing

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Endoscope reprocessing is often ineffective, and microbes frequently remain on endoscopes after the use of high-level disinfectants (HLDs). Several factors impact reprocessing effectiveness, including non-adherence to guidelines, use of damaged endoscopes, use of insoluble products during endoscopy, insufficient cleaning, contaminated rinse water, and inadequate drying before storage. Our team suspected that issues with HLD chemistries and monitoring could also contribute to reprocessing failures. We conducted a mixed-methods analysis of published literature, our interviews with frontline personnel, and evidence from our previous studies. The evidence showed that reusable HLDs commonly failed tests for minimum effective concentration (MEC) before their maximum usage periods. MEC tests also detected failures associated with single-use HLDs that did not fully deploy. These failures were due to product issues, process complexities, and personnel non-adherence with guidelines and manufacturer instructions. HLDs will likely continue to be used for the foreseeable future. More research is needed to assess real-world practice patterns related to the high-level disinfection step and MEC testing and to establish more realistic usage periods for reusable HLD chemistries. Manufacturers and researchers should evaluate the ability of technological solutions and engineered safeguards to overcome human error. Recognition of the need for quality improvement is growing, and infection preventionists should take action to build on this momentum and collaborate with manufacturers, endoscopists, and reprocessing personnel to improve the effectiveness of high-level disinfection.

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Over the past 10 years, evidence has mounted that endoscope reprocessing is frequently not effective. Studies have documented microbial growth rates of 16%,¹ 35%,² 41%,³ 47%,⁴ 58%,⁵ 60%,^{6–8} 64%,⁹ and 71%¹⁰ in samples from flexible endoscopes following the use of high-level disinfectants (HLDs). Even when double high-level disinfection was performed per recommendations from the US Food and

Drug Administration (FDA)¹¹ and experts,^{12,13} culturable aerobic bacteria were present 5%–40% of the time.^{1,8,14,15}

Reprocessing failures can have dire consequences for patients, and infections have been associated with ureteroscopes,^{3,16,17} cystoscopes,^{18,19} bronchoscopes,^{20–22} colonoscopes,²³ gastroscopes,²⁴ and duodenoscopes.^{25–30} Attack rates have been high, ranging from 6% for bronchoscopes²¹ to 35% for duodenoscopes²⁵ and ureteroscopes.¹⁶ Post-endoscopy infections remain common (>3%) even when patients receive prophylactic antimicrobials.^{3,16,17}

Our team has studied endoscope reprocessing effectiveness since 2007, and we have assessed reprocessing practices and outcomes for more than 900 endoscopes across the United States. We identified several factors that contribute to reprocessing failures, and other studies have echoed our findings. These factors include the following:

1. Human factors contributing to non-adherence with guidelines, standards, and manufacturer instructions for use (IFU)^{5,10,16,23,25,31–34}
2. Clinical use of endoscopes with visible damage^{4,5,7,10,26,29,34–36}

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3. Use of products that may interfere with reprocessing (simethicone, lubricants, and tissue glue)^{37–40}
4. Presence of residual soil after manual cleaning^{4,5,7,9,20,25,41}
5. Rinse-water quality issues^{5,6,10,42}
6. Retained moisture in fully reprocessed endoscopes.^{5,7,10,36,40}

In this context, reprocessing failures would not be unexpected. However, reprocessing failures have also been documented when no breaches were apparent.^{3,28,29,43}

The recent literature has not included evidence exploring problems with the high-level disinfection step itself. Our research team has observed improper high-level disinfection practices during site visits, including the use of expired products, improper HLD temperature, inadequate testing for the minimum effective concentration (MEC) of HLDs, and improper storage of MEC test strips. The purpose of this report is to describe the steps we took to evaluate the prevalence and nature of problems specific to HLD use and monitoring.

DATA SOURCES AND ANALYTIC METHODS

We performed a mixed-methods analysis involving a grounded theory approach to identify additional factors that might be contributing to high-level disinfection failures. Grounded theory is a method used to determine what is occurring in the field by interviewing participants, making qualitative observations, and identifying patterns from diverse data sources.^{44,45}

Literature review

A literature search was conducted using PubMed. Search terms included endoscopes, high-level disinfection, minimum effective concentration, minimum recommended concentration, test strip, indicator strip, *ortho*-phthalaldehyde (OPA), glutaraldehyde, peracetic acid, hydrogen peroxide, and automated endoscope reprocessor (AER) manufacturers and models. Our team also reviewed manufacturer IFU and searched FDA and Centers for Medicare and Medicaid Services (CMS) databases for reports related to high-level disinfection practices.

Interviews with frontline personnel

Semi-structured interviews with 7 experienced infection prevention, sterile processing, and endoscopy staff from diverse geographies

and institutions were conducted to learn more about their real-world experience with HLDs, AERs, and MEC testing. Interviewees described their AERs, HLDs, current practices, and perspectives on challenges with high-level disinfection. Interview notes were analyzed using grounded theory to identify themes and patterns in the responses.

Retrospective review of data from audits and site visits

During our previous studies,^{5–7,9,10,31,34,37,38} we recorded results and incidental findings on checklists and audit forms. These archived records were reviewed using grounded theory analysis.

Survey of sterile processing technicians and managers

In 2018, our team performed statistical analysis on data derived from an extensive online survey on endoscope reprocessing we conducted in collaboration with the International Association of Healthcare Central Service Materiel Management (IAHCMM).³³ Completed surveys were submitted by 2,334 members from the United States and 11 other countries. The dataset did not include any personal identifiers and provided a cross-sectional view of current reprocessing practices and perspectives among respondents who were largely certified sterile processing professionals and worked in hospitals.³³

HLD AND MEC TESTING GUIDELINES AND IFU

The survey found that the most commonly used HLDs were OPA, hydrogen peroxide, peracetic acid, and glutaraldehyde.³³ Our review of IFU uncovered substantial variation in HLD concentrations, exposure times, temperatures, and allowable use periods (Table 1). Several interviewees reported using HLDs that were kept in large reservoirs, reused for various periods of time, and then discarded and replaced (reusable HLDs). Others reported using concentrated solutions that are dispensed from large jugs during each cycle (single-shot HLDs) or small single-use containers of HLD that are diluted for each high-level disinfection cycle and discarded afterward (single-use HLDs).

According to the IFU, each HLD has a manufacturer-labeled expiration date indicating its shelf life. There is an additional expiration date that technicians record on each container when it has been opened, as well as a maximum reuse period that defines how long the solution can be used repeatedly (Table 1). For example, the manufacturer instructions for Acecide-C peracetic acid state that the HLD

Table 1
HLD characteristics for automated reprocessing

Chemistry	Product	Type*	Concentration	MEC	Exposure time (min)	Exposure temperature	Maximum reuse period (d)
OPA	ASP Cidex OPA ⁴⁶	Reusable	0.55%	0.3%	5	25°C	14
	ASP Cidex OPA-C Concentrate ⁴⁷	Single-shot	5.75%	0.055%	5	50°C	NA [†]
	Metrex MetriCide OPA Plus ⁴⁸	Reusable	0.6%	0.3%	5	25°C	14
	Medivators Rapicide OPA/28 ⁴⁹	Reusable	0.575%	0.35%	5	20°C	28
	Medivators Rapicide PA 30°C ⁵⁰	Single-shot	0.105 g	0.085%	5	30°C	NA [‡]
PA	Steris S40 ⁵¹	Single-use	35%	0.182%	6	45.5–60°C	NA
	Olympus Acecide-C ^{52,53}	Reusable	0.31–0.34%	0.2%	7	20°C	5
	ASP Cidex Activated Glutaraldehyde ⁵⁴	Reusable	2.4%	1.5%	45	25°C	14
Glutaraldehyde	Medivators Rapicide ⁵⁵	Reusable	2.5%	1.5%	5	35°C	28
	Metrex MetriCide ^{56,57}	Reusable	2.6%	1.5%	45	25°C	14
	Metrex MetriCide 28 ^{58,59}	Reusable	2.5%	1.8%	90	25°C	28
	Olympus Aldahol 1.8 ⁶⁰	Reusable	3.4%	1.8%	10	20°C	14
	Steris Revital-Ox RESERT ⁶¹	Reusable	2%	1.5%	8	20°C	21
H ₂ O ₂							

H₂O₂, hydrogen peroxide; HLD, high-level disinfectant; MEC, minimum effective concentration; NA, not applicable; OPA, *ortho*-phthalaldehyde; PA, peracetic acid.
 *Reusable HLD, a large amount of HLD is placed in a reservoir and reused for multiple cycles; single-use HLD, HLD concentrate in a single-use container is diluted for use and discarded following each cycle; single-shot HLD, a small amount of “fresh” concentrated HLD is taken from large jugs and diluted for each cycle and the bottle can be used within 21 or 80 days after opening.
[†]Single-shot HLD used within 80 days after opening.
[‡]Single-shot HLD used within 21 days after opening.

solution may be reused for up to 5 days or until the MEC test fails, whichever occurs first.

IFU state that MEC test strips should be immersed in the HLD for a specified dip time, and color changes should be interpreted after a certain amount of time (read time) (Table 2). Current guidelines^{62,63} and IFU^{64–70} recommend MEC testing during each reprocessing cycle to ensure that the HLD concentration exceeds the MEC, which is the level required to “achieve the claimed microbicidal activity.”⁶² Each HLD requires a different test strip that has particular IFU and pass/fail conditions, manufacturer-defined shelf life, open-container expiration date, and storage requirements (eg, keeping the container closed; maintaining a certain temperature, humidity, or light level).^{64–71} Many test strips also require quality control checks on each newly opened bottle, which generally involves testing full-strength and diluted HLD to ensure that the test strips provide correct readings.^{65,67–69,71–73}

HLD AND AER FAILURES

Our literature review uncovered several studies from the 1980s to the early 2000s that assessed the efficacy and other features of various HLDs for flexible endoscopes.^{74–80} Two studies detected microbes after high-level disinfection.^{75,76} Four articles assessed the dilution of reusable HLDs over time,^{77–80} highlighting the necessity of MEC testing to ensure effectiveness.

To determine the extent of problems with HLD concentrations, we asked frontline staff about their experience with AER cycles and high-level disinfection failures identified through MEC testing. Two interviewees reported that MEC testing was critical because their HLDs generally did not reach the maximum use period. At one site, 28-day glutaraldehyde consistently failed within 21 days. A site with 14-day glutaraldehyde had to change the HLD every week instead of every 2 weeks. One manager speculated that early HLD failures were due to dirty or wet endoscopes being put into the AER, which could dilute the glutaraldehyde.

Interviewees also reported HLD concentration issues with single-use peracetic acid cups. AER cycles failed when the powdered buffer and concentrated peracetic acid in the cup did not fully deploy and left thick residue in the cup or AER basin. They reported that shipping and storage conditions may have affected HLD usability.

These anecdotal reports were reinforced by IAHCMM survey responses. Nearly half (46%) of respondents experienced AER cycle failures in the previous month, and 16% documented more than 3 failures during that time frame.³³ Reasons for AER failures included running out of chemicals and issues with temperature control, water filters, fluid flow rates, channel blockage, and leak test failures. These factors can impact HLD effectiveness.

NON-ADHERENCE TO HLD GUIDELINES AND STANDARDS

We have observed widespread non-adherence to minimum standards for HLD use and MEC testing at many sites. In one study, steps were skipped or done incorrectly for 99% of the endoscopes,³¹ and substandard high-level disinfection practices were among the errors made. Our literature review identified several early studies that described suboptimal MEC testing practices. Two 1992 studies revealed that MEC testing was not performed in 73%⁸¹ to 76%⁸² of sites. A 2003 study found that test strips were not user friendly and endoscopy staff interpreted them incorrectly >12% of the time.⁷⁴ Researchers in 2010 evaluated reprocessing practices at 20 Brazilian facilities and found that 80% of endoscopes were not exposed to HLDs for the proper amount of time, and MEC testing was performed in only 15% of reprocessing cycles.⁸³ We were unable to identify recent prospective studies on real-world high-level disinfection practices or MEC testing. Most (79%) respondents to our IAHCMM survey indicated that MEC tests were performed every cycle, but 17% reported testing MEC less often, and 4% tested less than once per day or never performed MEC tests at all. Only 51% reported documenting MEC results.³³

Our review of FDA and CMS reports revealed that manufacturers and surveyors have also identified non-compliance with high-level disinfection practices and MEC testing (Table 3). These errors have negatively impacted patient outcomes. One FDA outbreak report described 2 cystoscopy patients who developed *Klebsiella pneumoniae* infections that required intravenous antibiotics.⁹³ Investigators reported that leak testing was not done, and MEC was tested only once every 2 weeks. A CMS report described a situation where an infection preventionist discovered that expired HLDs had been used to reprocess endoscopes.⁹⁴ Surveyors cited the institution for using endoscopes reprocessed with expired HLDs on 45 patients, including one with a history of hepatitis. They concluded that the facility's failure to adequately investigate the incidents “potentially jeopardized the health and safety of the patients involved.” Given the lengthy period of time during which the high-level disinfection practices may not have been appropriate, 3,400 patients were notified about their potential exposure to bloodborne pathogens.⁹⁵

WHY IS NON-ADHERENCE SO PREVALENT?

Complex IFU and inadequate training

One common barrier described by frontline staff was reprocessing IFU complexity. Most IAHCMM survey respondents (84%) had read IFU for flexible endoscopes, but one-third of them reported that the IFU were not understandable or feasible.³³ Recent FDA post-market

Table 2
MEC testing instructions for various manufacturers

Chemistry	Brand	Dip time (s)	Read time (s)	Pass	Fail
OPA	Medivators Rapicide OPA/28 ⁶⁴	3	90	Green	Blue
	ASP Cidex OPA ⁶⁷	1	90	Purple	Any blue
	Metrex MetriCide OPA Plus ⁷²	2	60	Magenta	Any yellow
	Medivators Rapicide PA ⁷¹	1	30–60	Black	Any other color
PA	Steris Verify ^{66,*}	360	0–1,800	Pink	Blue, gray/beige or not clearly pink
Glutaraldehyde	Olympus Acecide-C Test ⁷⁰	3	10 [†]	Black	Any white
	ASP Cidex Solution ⁶⁸	3	75	Purple	Any orange
	Metrex MetriTest 1.8% and 1.5% ⁷³	2	60	Purple	Any yellow
	Olympus Aldechek ⁶⁹	2	60	Purple	Any yellow
H ₂ O ₂	Steris RevitalOx RESERT R60 ⁶⁵	2	60	Blue or purple	Any pink

H₂O₂, hydrogen peroxide; MEC, minimum effective concentration; OPA, ortho-phthalaldehyde; PA, peracetic acid

*The test strip is placed in the automated endoscope reprocessor for the duration of the cycle and should be read immediately or within 30 min (1,800 s) of cycle completion.

[†]The 10-s read time consists of removal of excess fluid within 3 s and reading the strip 7 s after removal of excess fluid.

Table 3
CMS and FDA reports of MEC or HLD non-compliance

Report ID	Year	Expired MEC strips	Expired HLD	MEC bottle stored open	Improper HLD practices	Improper MEC testing	Missing records
CMS 15079 ⁸⁴	2017		✓		✓	✓	✓
CMS 14533 ⁸⁵	2017			✓			✓
CMS 24631 ⁸⁶	2018					✓	✓
CMS 21220 ⁸⁷	2018	✓			✓		✓
FDA 7182901 ⁸⁸	2017					✓	
FDA 8072138 ⁸⁹	2018		✓				
FDA 7558700 ⁹⁰	2018					✓	
FDA 7833925 ⁹¹	2018		✓		✓		
FDA 7639885 ⁹²	2018	✓					✓
FDA 8364744 ⁹³	2019					✓	

CMS, Centers for Medicare and Medicaid Services; FDA, Food & Drug Administration; HLD, high-level disinfectant; MEC, minimum effective concentration.

surveillance studies into human factors that impact duodenoscope reprocessing effectiveness found that IFU are “difficult for reprocessing staff to comprehend and follow.”⁹⁶ Concerns about IFU complexity are amplified by insufficient training. Most survey respondents (70%) received a week or less of training before beginning to reprocess endoscopes independently.³³ Only 46% received model-specific training that covered unique steps required for reprocessing each type of endoscope used in their facilities. Multiple types of AERs were in use at 17% of facilities, and the use of multiple systems increased the number of IFU that technicians must understand and remember. This also raises the possibility of using the wrong combination of HLD chemistries and MEC testing materials.

Time pressure and workflow

Most survey respondents (70%) reported feeling pressured to reprocess endoscopes more quickly, and 26% reported one of their biggest challenges was not having enough time for reprocessing.³³ Our studies have found that proper endoscope reprocessing requires well over 1 hour per endoscope^{32,97}; yet, frontline staff reported being expected to turn endoscopes around much more rapidly. In addition, 17% of respondents reported skipping steps or doing them more quickly than they should due to time pressure. Two interviewees reported that manufacturer sales representatives had recommended shortening or disabling AER cleaning and rinsing cycles in order to save time and improve turnaround. During previous studies, we discovered that AER manufacturers' representatives had disabled AER cleaning cycles in 2 other hospitals.^{5,10} Incidents where AERs were disabled or cycles were improperly programmed have also been reported to the FDA.^{98–100}

Our review of IFU determined that MEC testing requires substantial time (1 to 8+ minutes) (Table 2). Performing MEC tests was perceived as a “hassle” by 170 survey respondents, and 280 disliked changing HLDs. Interviewees said that responding to failed MEC tests was time intensive, as technicians had to interrupt their workflow to dispose of the used HLD and container, refill and reprogram the AER, and possibly rerun the cycle. Failures of single-use HLD cups were also disruptive, and technicians reported having to clean concentrated peracetic acid out of AER basins before the cycle could be rerun. Every MEC test failure requires documentation before technicians can continue with other duties. For these reasons, interviewees indicated that technicians disliked discovering failed MEC tests. Interviewees also reported that technicians commonly had difficulties interpreting test strip color changes and making pass/fail determinations. One interviewee said, “Dipsticks are hard to read—the results aren't black and white and that's a huge problem.” In addition, institutions must ensure that all personnel responsible for tasks that require color interpretation are able to discern the colors.¹⁰¹ According to interviewees, when a colorblind staff member is on duty, other

personnel have to interpret MEC tests, which is distracting and takes additional time.

Occupational health concerns

Concerns about chemical exposure were frequently cited as a reason why technicians might not adhere to HLD guidelines. The IAHCMM survey found that 47% of respondents were bothered by odors in the reprocessing area.³³ When technicians change the HLD, they may be exposed to vapors from highly concentrated chemistries. Safety data sheets state that glutaraldehyde and peracetic acid can cause respiratory issues.^{102,103} During site visits, we frequently noticed strong HLD odors in reprocessing areas even when the HLD was not being changed, possibly due to insufficient air changes or poor ventilation mechanisms.

HLDs can cause burns¹⁰⁴ and skin¹⁰⁵ and lung¹⁰⁶ irritation, and FDA reports describe injuries related to HLD exposure. Some interviewees stated that some technicians are afraid of peracetic acid and therefore dislike working with it, and others disregard safety concerns and fail to wear proper personal protective equipment when working with HLDs. One infection preventionist described a technician who neglected to wear a face shield and sustained permanent eye damage due to a peracetic acid splash.

One interviewee said that changing HLD was a grueling process because each AER held 8 gallons of 14-day glutaraldehyde that generally had to be changed weekly due to failed MEC tests. Technicians and the safety management team were uncomfortable with the occupational health risks associated with this regimen, and the site was switching to peracetic acid. In the IAHCMM survey, 459 respondents reported that changing chemical solutions caused them pain, and 26% reported pain that was significant or so extreme that they could not complete the task.³³

WHERE DO WE GO FROM HERE?

We are troubled by mounting evidence demonstrating that HLD effectiveness is suboptimal in real-world settings.^{1–10,14,15} Previous research has established that multiple factors contribute to reprocessing failures.^{16,20,26,40,42} Our first endoscope reprocessing study (2008–2009) found that 27 of 36 participants (75%) had been pressured to work quickly, and a technician admitted skipping steps.³¹ Occupational health problems were common, with respiratory issues reported by 18% and physical discomfort by 50%. These health problems were so severe that 25% missed work, and 30% reported the symptoms interfered with their ability to function at work and/or at home. Since then, little progress has been made, and we have repeatedly observed the same problems at study sites and on audits.

Clearly, these long-standing barriers to adherence and overall reprocessing effectiveness must be addressed; however, the groundbreaking research described in this manuscript identified additional

problems specific to the high-level disinfection step and MEC testing that ensures the chemistries are strong enough to reliably eliminate microbes. As Rutala and Weber¹³ stated, the margin for error with high-level disinfection is simply not large enough to tolerate any deviations from optimal practices. They have recommended a shift toward sterilization, and we agree that sterilization may be necessary for improving patient safety. In the meantime, high-level disinfection will continue to be used by many institutions, and it is essential to address the quality issues described in this paper.

Given our findings, we recommend that multisite studies and ongoing surveillance be conducted to assess real-world practice patterns and determine the nature and prevalence of breaches related to the high-level disinfection step and MEC testing. Research should also be done to establish realistic usage periods for reusable HLD chemistries in real-world settings. In addition, researchers should assess the ability of technological solutions such as automation and engineered safeguards (eg, AERs that shut down when anything does not meet manufacturer criteria) to overcome shortcomings that have been attributed to human error. For these technological innovations to be successful, it is essential that manufacturers and their representatives be partners in striving for excellence in the field. Neither company representatives nor customers should seek to deviate from IFU or to shorten automated cycles to save time. Before implementing time-saving or cost-cutting measures, infection prevention and reprocessing managers should review evidence provided by the manufacturer that reprocessing is still effective when these steps are skipped or processes are truncated. Ideally, manufacturers and facility personnel will provide mutual support and accountability for ensuring that practices align with guidelines and IFU.

We see a strong parallel between endoscopy and aviation in terms of high stakes for patients and passengers as well as complex protocols and procedures. Aviation has addressed these challenges by cultivating an environment of safety, accountability, and discipline. Aircraft manufacturers have the responsibility for building safe aircraft, and everyone from pilots to mechanics and support personnel undergo mandatory training, certification, and use checklists on every flight. However, adoption of similar measures in the medical field has lagged. One explanation for this difference may be that on-board airline personnel assume the same risk as passengers, whereas health care personnel do not bear the same risk from contaminated endoscopes as their patients.

Leaders in pulmonology and otolaryngology are beginning to recognize the risk of infection from improper reprocessing practices and call for comprehensive solutions.^{107–109} As Gawande¹¹⁰ stated, when quality improvements are not implemented, the cause is generally not laziness or unwillingness to change, but rather the “reason is more often that the necessary knowledge has not been translated into a simple, usable, and systematic form.” Given the current situation, it is essential for infection preventionists to leverage this momentum and take the lead in coordinating efforts of endoscopists, reprocessing personnel, and others to implement robust quality management programs that address all of the factors that impact HLD effectiveness.

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