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Better Instructions for Use to Improve Reusable Medical Equipment (RME) Sterility

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Objective: The objective was to evaluate human-factors-based instructional aids on endoscope reprocessing.

Background: The project stems from recent failures in reprocessing (cleaning) endoscopes, contributing to the spread of harmful bacterial and viral agents between patients. A previous study discovered three themes that represent a majority of problems: (1) lack of visibility (parts and tools were difficult to identify), (2) high memory demands, and (3) insufficient feedback.

Method: In an effort to improve completion rate and reduce error, the authors designed instructional aids utilizing human factors principles that would replace existing manufacturer-provided visual aids. Then, they conducted a usability test, which compared the endoscope reprocessing performance of novices using the standard manufacturer-provided visual aids and the new instructional aids.

Results: Participants in the experimental group successfully completed 87.1% of the reprocessing procedure with the use of the instructional aids, compared to 44.7% in the control group using only existing support materials. Of 60 subtasks, 27 showed significant improvement in completion rates.

Conclusion: When given an instructional aid designed with human factors principles, participants were able to more successfully complete the reprocessing task. This resulted in an endoscope that was more likely to be safe for use on patients.

Application: The human factors design elements utilized to create the instructional aids could be transferred to a dynamic electronic-based system to improve patient safety.

Keywords: human factors, patient safety, instructions for use, IFU, reusable device sterility, reusable medical equipment, RME, infection, outbreak

In the United States, approximately 15 million gastrointestinal (GI) endoscopies are completed annually (Humphrey & Kovach, 2006). Endoscopy is a minimally invasive procedure used to diagnose and treat a number of medical disorders. Despite a low incidence of infection, there are more health-care-associated outbreaks linked to contaminated endoscopes than any other medical device (Rutala & Weber, 2004).

Contaminated endoscopes generally result from improper reprocessing and the cleaning and disinfection process to eliminate harmful agents, a subject that has gained media attention and raised concern for patient safety. Endoscopes are often used on multiple patients each day, risking exposure to infected bodily fluids that could be transmitted between patients. To complicate matters, endoscopes have long, dark, narrow channels that create a perfect environment for viruses and bacteria to breed. Their complex design and delicate construction materials make them difficult to reprocess (Ninemeier, 2003). In one study, nearly 24% of the bacterial cultures from the internal channels of 71 GI endoscopes grew significant colonies of bacteria after reprocessing (Rutala, Weber, & Healthcare Infection Control Practices Advisory Committee, 2008). This could be the result of leftover contaminating organisms, or bioburden (Ishino, Ido, Koiwai, & Sugano, 2001). In January 2009, 38% of the facilities of one large hospital system reported they were not in compliance with the manufacturer's instructions for reprocessing endoscopes (Department of Veterans Affairs Office of Inspector General, 2009). If an endoscope is improperly reprocessed, it can lead to the transmission of infectious diseases, including HIV, Hepatitis B, and Hepatitis C (Mehta et al., 2006; Weber & Rutala, 2001). As a result, it is imperative to identify problems with reprocessing and to develop evidence-based solutions. This article

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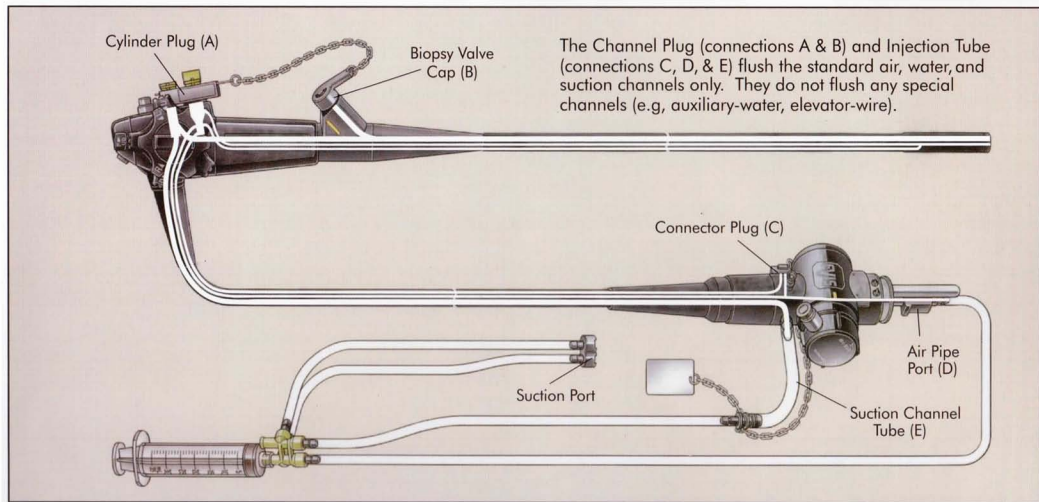


Figure 1. Flexible endoscope and reprocessing equipment. Image courtesy of Olympus America Inc.

discusses human factors principles for reducing reprocessing problems, how we applied the principles to design an instructional aid, how we tested this aid, and the results of the test. We then discuss the implications of this approach for further reduction of infections caused by poorly reprocessed reusable medical equipment (RME).

Reprocessing

Endoscope reprocessing procedures, like the device itself, are complex. Figure 1 shows a common flexible endoscope and some of the equipment used during reprocessing.

Reprocessing procedures typically include the following sequential subtasks: precleaning, leak testing, cleaning, disinfection or sterilization, rinsing, drying, and storage (Rutala & Weber, 2004). The cleaning portion of the procedure is accomplished manually or mechanically using water with an enzymatic detergent. Thorough cleaning is essential because inorganic and organic materials that remain on the internal and external surfaces of instruments interfere with the effectiveness of the disinfection and sterilization processes. The steps, described later, summarize what is often a 75-page manufacturer's instruction manual or a 30-page standard operating procedure (SOP).

- **Precleaning:** Completed bedside immediately following patient procedure. Suction detergent or water (as per manufacturer's instructions) through endoscope channels. Remove valves and removable parts and soak in detergent solution. Transport all equipment to reprocessing area.
- **Leak testing:** Connect the scope to an air source and submerge it in clean water to check for a stream of air bubbles, which indicate damage to the scope.
- **Brushing and flushing:** Immerse in detergent (usually enzymatic cleaner) and mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with detergent and water.
- **Disinfection:** Immerse the endoscope in disinfectant and perfuse disinfectant into all accessible channels and expose for a recommended amount of time.
- **Sterilization:** Sterilize, to destroy or eliminate microbes, using pressurized steam, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, or liquid chemicals.
- **Rinsing (for liquid chemicals only):** Rinse the endoscope and all channels with sterile or filtered water.
- **Drying:** Rinse the insertion tube and inner channels with alcohol and dry with forced air.
- **Storage:** Store the endoscope vertically.

TABLE 1: Five Critical Subtasks of Reprocessing in Jolly et al. (2012)

Task	Reprocessing Error	Potential Consequence	Mean Completed with Error (%)
Observing scope for leak	Incomplete leak detection	Costly damage to scope	83.3
Suctioning detergent	Channels not completely flushed	Remaining bioburden	54.2
Brush instrument channel	Channel not completely brushed	Remaining bioburden	95.8
Attach channel plug/ injection tube	Channels not completely flushed	Remaining bioburden or detergent	95.8
Drying	Channels left moist	Bacterial or viral growth in internal channels	75.0

The procedure is time-consuming, physically engaging, and cognitively demanding. Each hospital may have several models of GI endoscopes, in addition to bronchoscopes, laparoscopes, cystoscopes, arthroscopes, and others. Each has its own reprocessing method, instructions, and SOPs. A technician will need to identify each type, make, model, and apply the appropriate procedures. Furthermore, depending on the facility, an individual technician could reprocess as many as 40 endoscopes per day.

Previous Studies

To identify potential human factors issues between the human user and elements of the reprocessing system that may result in error, Hildebrand et al. (2010) conducted a heuristic evaluation of the endoscope reprocessing procedure. Using human factors principles modified for the medical field (Zhang, Johnson, Patel, Paige, & Kubose, 2003), this study identified 277 heuristic violations in the reprocessing procedure, 76% of which came from violations of error (systems should be designed to prevent mistakes), memory (users shouldn't be required to remember too much information), and feedback (cues should be given keeping the user apprised of their status in the task). This study suggests that the current reprocessing procedures and device design are problematic and needed to be investigated further.

Next, Jolly et al. (2012) investigated the performance of naïve users when reprocessing

endoscopes. Participants were nursing students and had a basic understanding of infection control principles but had no prior experience reprocessing endoscopes. Participants simulated the reprocessing of an endoscope with the equipment and support materials commonly available to technicians: the SOPs and manufacturer-provided visual aids. Participants were provided with only a brief orientation to the reprocessing procedure and allowed to utilize the SOPs and manufacturer-provided visual aids as they saw fit. The results were disastrous: None of 24 participants successfully reprocessed an endoscope, and on average fewer than half of the procedure's subtasks were completed without error. Of the 76 subtasks tested, 5 were identified as being particularly critical, based on (a) the number of participants who failed to complete the subtask, (b) how that failure affected subsequent subtasks in the procedure, (c) how representative the subtask was of the task as a whole, and (d) potential risk of infection. Table 1 summarizes these critical subtasks and identifies potential consequences as a result of their incompleteness.

The source of error for these subtasks, as well as the majority of problems in the reprocessing procedure, fell into three common themes directly related to the top three heuristic violations (error, memory, and feedback) found in Hildebrand et al. (2010). The term *error* was found to be ambiguous, and as such error violations were examined further and found to be

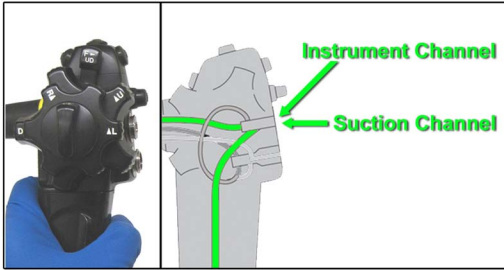


Figure 2. Flexible endoscope with multiple channels accessed via a single port.

most related to lack of visibility of tools or parts. These three common themes, (a) lack of visibility, (b) high memory demands, and (c) insufficient feedback, are described next.

Lack of visibility. If a part or tool is difficult to identify or see clearly, it makes the task difficult to complete. In this test participants committed several errors because of poor contrast or positioning of a label, the lack of a label, a poor match between instructional diagrams and the product, and critical elements of the endoscope being hidden from view. Figure 2, for example, illustrates two internal channels hidden from view that must be brushed during the reprocessing procedure and are accessed via a single port. Only 1 of 24 participants brushed both channels.

High memory demands. Reprocessing involves dozens of parts, conflicting visual aids, and more than 200 sequential steps. The volume of materials and steps alone is enough to tax memory, especially if a user was interrupted. In addition, the names of parts and tools, as well as part numbers, are long and similar to one another. For example, SOPs for a single endoscope referenced the following parts and tools: suction machine, suction canister, suction port, suction connector, suction tube, suction cylinder, suction cleaning adapter, and suction valve. The use of similar part names caused confusion and contributed to error.

Feedback. Without cues signaling the successful completion of a step, participants were confused about their place in the instructions and unsure about whether they were doing the right thing at the right time. For example, the SOPs had no pictures and did not reference any

manufacturer-provided visual aids. Thus, users were unable to receive visual feedback of how a tool should look when attached correctly or how to properly use that tool.

The current study focused on the development and evaluation of support materials that aimed to address these themes by increasing visibility, lowering memory demands, and providing better feedback. One may question why our focus lies on creating user-friendly instructions for a user-unfriendly tool instead of re-designing the endoscope itself. Currently, we have little control of the manufacturer design of the endoscope and reprocessing tools. To make a positive impact in the short term, we chose to first revamp the support materials. Our long-term goal is, however, to affect endoscope redesign in a way that makes them easier to reprocess and safer for the patient.

Basis for Instructional Aid Design

Norman (1993) stated, “The power of the unaided mind is highly overrated” (p. 43). Without external aids, our memory, thought, and reasoning are constrained. When well designed, external aids can complement our abilities, strengthen our mental powers, and help us overcome our own limits. However, in the case of reprocessing, poorly designed support materials contributed to improperly cleaned endoscopes (Jolly et al., 2012).

We examined the existing support materials and discovered that the SOPs often failed to correspond accurately with the manufacturer-provided visual aids (occasionally contradicting them) and lacked easy-to-understand instructions. SOPs are typically written to fulfill an organizational requirement rather than to provide utility to technicians. Furthermore, the frequency of use and availability of the SOPs vary widely between facilities. As additional support to the reprocessing procedure, endoscope manufacturers provide visual aids in a poster format. When evaluating these visual aids, we found they oversimplify the procedure, making it impossible to rely on them exclusively. For example, the entire leak testing section, requiring 25 steps in the SOPs, is described in one ambiguous slide (Figure 3). In fact, a warning on the visual aids states that they are incomplete

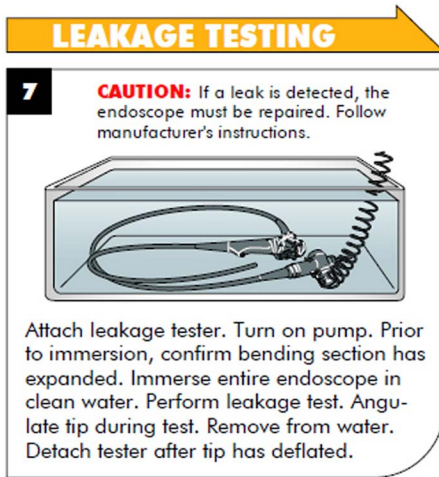


Figure 3. Manufacturer slide for leak testing.

and that the technician should reference the manufacturer instruction manual, which is often not easily accessible.

Instructional Aid Development

To begin the design process, we reasoned that the instructional aids should guide a novice user through the entire reprocessing procedure. This simulates a real-life, worst-case situation in which a new reprocessing technician was left alone or needed to reprocess a scope he or she had not yet seen, but had no one else with whom to consult. We chose a poster format for the instructional aids as a proof of concept and limited them to fewer than 20 slides each. To understand the reprocessing procedure, we gained hands-on knowledge of reprocessing by being trained personally by multiple experts at several hospitals. We created instructional aids for only the leak testing, brushing, and flushing portions of reprocessing, as the steps in these tasks are representative of the reprocessing task as a whole. The design process was iterative, taking many sessions to produce a product that was ready to test. We utilized a number of design principles, recognizing that there are no hard and fast rules for design, but that the implications of our design solutions must be carefully considered before being applied (Wickens, Lee, Liu, & Gordon Becker, 2004). Table 2

details many of these principles, all of which focused to varying degrees on our primary goals of increasing visibility, reducing memory demands, and providing sufficient feedback.

Increasing visibility. Following the principle of consistency (Nielsen, 1994), green text and arrows were used to express primary instructions throughout the instructional aids. Through a consistent visual design, users are able to quickly initiate a visual search to identify where they have been and where they are going. We color coded each of the three tasks (leak testing, brushing, and flushing) to highlight the relation of steps within a task and the difference of steps between tasks. Because 8% of males are missing red–green channels and have trouble distinguishing between red and green (Judd, 1943), we used color combinations that were salient and dual-coded all instructions (graphics and text). Often, vision relies on the ability to discriminate signals rather than to detect or identify any one signal (Wickens et al., 2004). As such, the graphics were designed to enable users to discriminate between tools and areas of the endoscope without having to identify a part name or number. We did this by enhancing or suppressing different aspects of images to direct the user to the needed item or tool, making the name or part number less relevant. Instructions for the picture seen in Figure 4 would have been “Remove the suction valve (MH-443) from the suction port of the endoscope and place it in the sink,” which would have been more difficult to understand without a picture and would have required identifying the valve and port separately.

Reducing memory demands. We limited the number of items users must keep in working memory or retrieve from long-term memory. This reduces memory demands by replacing memory (knowledge in the head) with visual information (knowledge in the world; Norman, 1988). Accordingly, the instructional aids display the endoscope and its tools from a first-person point of view, which reduces the need for mental rotation. We also employed a common font, Arial, throughout the aids, in addition to using mixed case and complete words rather than abbreviations (Wickens et al., 2004). The vocabulary was designed to be remembered easily by

TABLE 2: Design Principles Emphasized in Instructional Aid Creation

Design Principle	Purpose	Implication
Pictures and words	Position visuals and corresponding text in close proximity	Visuals with text improve comprehension
Vocabulary	Eliminate confusing vocabulary	Confusing vocabulary can lead to perceptual errors under stress
Automaticity	Provide text that can be read quickly with the use of familiar fonts, absence of abbreviations, and mixed cases (lower- and uppercase letters)	Focus remains on the task, not the formatting
Orientation	Match the perspective of the user	Eliminates mental rotation
Visual guidance	Direct users to important elements	Makes goals or tasks obvious
Discrimination	Use visuals to distinguish between elements	Allows visual identification of elements, reducing reliance on technical jargon and part numbers
Consistency	Use similar elements and structure	Enables user to learn rules once and apply them repeatedly
Simplicity	Separate tasks into their most basic elements	Reduces memory demands
Knowledge in the world	Put key information in easily accessible instructions	Reduces memory demands
Color coding	Highlight relationships or differences between elements	Dual coding with text and color maximizes understanding
Color blindness accommodation	Accommodate the 8% of males missing red/green channels who have difficulty distinguishing between the two	Color choice and use impacts user understanding

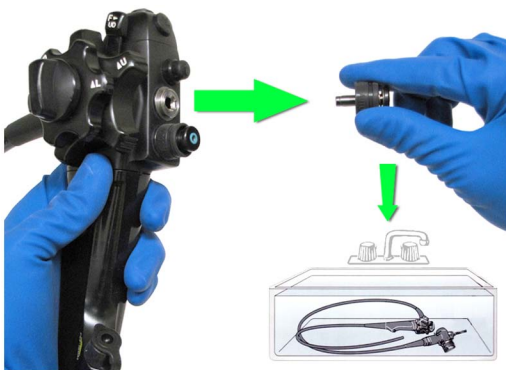


Figure 4. Suction valve removal.

removing confusing terms and technical jargon. For example, the SOPs refer to two brushes that are needed during reprocessing: the channel

cleaning brush and the channel opening cleaning brush (also called the valve/head brush). The new aids refer to them as the long and short brushes because one is over seven feet long and the other is less than four inches. In addition, vocabulary was changed to decrease perceptual errors under stress (e.g., “Do not remove the water resistant cap” could be read as “Remove the water resistant cap”). Finally, to accommodate the limits of working memory, each slide was simplified to achieve a single goal. For example, one slide has instructions showing the singular goal to “Turn on the MU-1 unit” instead of multiple goals like “Turn on the MU-1 unit and then attach the leak tester connector to the endoscope.”

Providing sufficient feedback. The instructional aids provide visual feedback of how a



Figure 5. Endoscope being properly depressurized.

part or tool should look when attached properly as well as alerting the user of auditory feedback to expect, where applicable. One example represents an audio signal (the hissing of escaping air) users should hear when the endoscope is depressurized (Figure 5). The instructional aid used for leak testing is shown in the appendix.

EXPERIMENT

We conducted an experiment to test the efficacy of the new instructional aids, hypothesizing that they would enable participants to complete the reprocessing task faster and with fewer errors than previous support materials.

METHOD

Participants

A total of 36 students (20 male, 16 female) between the ages of 18 and 54 participated for credit in psychology classes at a large university in the southwestern United States. Participants had no experience in reprocessing endoscopes.

Naïve participants were tested for several reasons. First, hospitals typically have a small number of reprocessing technicians, making it difficult to ensure confidentiality. Second, being unsure of the base rate of mistakes made by “expert” technicians, it made sense to test naïve users to identify the most confusing problems. Third, although it is common for technicians to receive some training in addition to having the support materials available, this is not always the case. For example, a report of one large hospital system revealed a nurse

serving the role of a reprocessing technician. Though she had received an orientation to reprocessing (Department of Veterans Affairs Office of Inspector General, 2009), she was observed improperly reprocessing one endoscope model that she admittedly had never seen reprocessed before.

To simulate this type of “worst-case” scenario, participants were provided with only a brief orientation to the reprocessing procedure and allowed to utilize the SOPs and manufacturer-provided visual aids as they saw fit.

Materials

This study was conducted in a simulated reprocessing lab at the test site noted previously. All the tools and materials necessary for endoscope reprocessing were visibly available to the participants at the beginning of the session. SOPs for the endoscope reprocessing procedure were placed in an accessible binder. The manufacturer-provided visual aids or the new instructional aids (depending on the condition) were attached to the wall at eye level, approximately 3 feet from participants. Clear plastic tubs approximately of sink size were used instead of traditional sinks to allow the experimenter to see the procedure from multiple angles.

Procedure

There were two conditions: the control condition, where participants reprocessed an endoscope using manufacturer-provided visual aids, and the experimental condition, where these visual aids were replaced with the new instructional aids. Participants were randomly assigned to each condition, 12 for the control and 24 for the experimental.

Participants were run individually. Each provided informed consent and release to photograph prior to the study. Participants then watched a 7-minute video consisting of clips from a Veterans Affairs (VA) orientation video for new reprocessing technicians that introduced them to endoscopes and the reprocessing procedure. The video was used to simulate a brief orientation that an expert might give to a new or acting technician. This was followed by a short background questionnaire.

TABLE 3: Mean Successful Completion Rates (and *SD*) for the Three Reprocessing Tasks Tested

Task	Control %		Experimental %		t test	df
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>		
Leak testing	72.9	16.9	85.9	8.7	2.505*	14
Brushing	33.3	20.5	87.2	12.9	8.312**	16
Flushing	36.0	21.5	88.0	11.6	7.825**	14
Total	44.7	17.1	87.1	8.5	8.115**	14

* $p < .05$. ** $p < .01$.

Next, participants were provided with all the necessary directions and materials to reprocess an endoscope and were allowed to briefly look over them and ask questions before beginning the reprocessing task. Time to complete each subtask, errors (deviations from the instructions), and requests for assistance were recorded. Comments, questions, and utterances made by the participant were also recorded.

Immediately following the reprocessing task, the test monitor prompted participants to discuss what they felt or thought about the task. Participants completed a short questionnaire and were encouraged to write additional comments on their experience of reprocessing an endoscope.

Next, the experimenter asked a set of debriefing questions and guided participants back through the procedure while prompting the participant to discuss each subtask of note. Finally, the experimenter explained the relevance of the study, answered any questions, and signed an educational credit form.

For analysis we divided the reprocessing procedure into three tasks: (a) leak testing, (b) brushing, and (c) flushing. Between-group differences of numbers of subtasks completed successfully and self-efficacy ratings were analyzed for statistical significance using independent sample *t* tests, and individual subtask completion rate was analyzed using chi-square tests. Degrees of freedom were calculated using the Welch-Satterthwaite equations for unequal sample sizes and unequal variance.

RESULTS

With the use of the instructional aids, 27 of the 60 subtasks tested were completed with

significantly fewer errors. Participants were able to complete 87.1% of the 60 subtasks free of error in the experimental condition, as opposed to 44.7% in the control condition, $t(14) = 8.115$, $p < .001$.

Completion Rate

As illustrated in Table 3, for each of the three reprocessing tasks tested, the experimental group showed a higher rate of successful completion than control. This supports the hypothesis that instructional aids designed with human factors principles significantly reduce reprocessing errors by naïve participants.

Of the five critical subtasks identified in Jolly et al. (2012), three were tested here. All three showed significant improvements in successful completion in the experimental condition (Table 4).

Although the experimental condition afforded a significant improvement over the control, nearly 42% of participants still failed to properly observe the endoscope for leaks. When checking for leaks, participants should keep the endoscope completely submerged in water and use the hand controls to bend the distal tip while looking for a stream of bubbles. Participants often failed to identify the distal tip or did not understand the importance of keeping the endoscope fully submerged. Even with multiple iterations of the instructional aids with special attention paid to this step, vital pieces of information were not conveyed. This illustrates the need for testing and revising instructional materials used in error-critical tasks.

The experimental condition showed significantly better rates of completion in 27 of the 60

TABLE 4: Successful Completion Rates for Three Critical Subtasks

Subtask	Control (%)	Experimental (%)	χ^2	Φ
Observe endoscope for leaks	0.0	58.3	10.50**	.54
Insert brush into instrument channel	33.3	91.7	4.90*	.37
Attach the channel plug and injection tube	0.0	91.7	16.50**	.68

* $p < .05$. ** $p < .01$.

subtasks. Table 5 compares completion rates for each of the subtasks in the brushing task. Completion rates showed similar trends for leak testing and flushing (additional data for these tasks are available from the authors). The control condition was not significantly superior in any of the tasks.

Using the themes found in Jolly et al. (2012) to represent the majority of problems in reprocessing (lack of visibility, high memory demands, and insufficient feedback), we identified which theme was primary and secondary for each subtask that showed significant improvement. The primary theme encompasses the principal explanation for the error, whereas secondary theme(s) represent contributing factors. Lack of visibility, high memory demands, and insufficient feedback were primary themes 70%, 30%, and 0% and secondary themes 81%, 52%, and 26%, respectively. This enabled us to speculate as to what benefits each instructional aid provided our participants. Note that errors previously associated with lack of visibility and high memory demands were the most improved by the addition of the instructional aids.

Completion Time

In all measured tasks, the experimental group conducted tasks significantly faster than the control group (Table 6).

Posttest Questionnaire

Participants rated their agreement with the following statements using a scale ranging from 1 (*strongly disagree*) to 5 (*strongly agree*; Table 7). The experimental group felt more confident that they had successfully reprocessed the endoscope and believed there were fewer memory demands than did controls. All other comparisons were not

significant. In response to the experimental group exhibiting more confidence, a correlational test was conducted between confidence ratings and performance, but no correlation was found in either group.

Participants also rated the ease or difficulty of select reprocessing tasks on a scale of 1 (*very easy*) to 5 (*very difficult*; Table 8). The experimental group rated the difficulty of all select tasks as less difficult. Those tasks rated as substantially easier with the use of the instructional aids were understanding the instructions, knowing where to attach the connectors of the injection tube, and identifying if the scope was pressurized.

Preferred Training Method

Participants were asked to rate the effectiveness of possible forms of training for reprocessing an endoscope on a scale of 1 (*most effective*) to 5 (*least effective*). It is not surprising that one-on-one training was rated most effective for both conditions. In the experimental condition, posters were rated significantly more effective than in the control condition, $t(20) = 2.20$, $p < .05$. In other words, participants rated posters more effective when using the new instructional aids and less effective when using the manufacturer-provided visual aids.

DISCUSSION

To reduce the possibility of infectious transmission to patients because of improperly reprocessed, contaminated endoscopes, this study identified problem areas within current instructions for use practices. It also developed and evaluated a potential evidence-based solution.

The human-factors-based instructional aids tested provided naïve users with better support as

TABLE 5: Successful Completion Rates for Subtasks in Brushing

Subtask	Control (%)	Experimental (%)	χ^2	Φ
Confirm addition of enzymatic cleaner	41.7	91.7	3.38	.31
Remove and immerse reusable parts	16.7	95.8	10.03**	.53
Set scope to free position	0.0	95.8	17.25**	.69
Wipe exterior of endoscope (keep immersed)	58.3	75.0	0.38	.10
Straighten endoscope bending section	8.3	95.8	13.23**	.61
Insert brush into instrument channel	33.3	91.7	4.90*	.37
Push brush through channel	33.3	91.7	4.90*	.37
Clean brush with fingertips	33.3	91.7	4.90*	.37
Remove brush correctly	8.3	83.3	11.05**	.55
Clean brush with fingertips	8.3	70.8	8.88**	.50
Insert brush into suction channel	75.0	100.0	0.64	.13
Push brush through channel	75.0	100.0	0.64	.13
Clean brush with fingertips	41.7	95.8	3.84*	.33
Remove brush correctly	50.0	87.5	1.84	.23
Clean brush with fingertips	33.3	83.3	3.86*	.33
Brush suction cylinder	58.3	62.5	0.03	.03
Turn brush and remove	66.7	87.5	0.51	.12
Clean brush with fingertips	25.0	79.2	5.07*	.38
Brush instrument channel port	58.3	95.8	1.64	.21
Turn brush and remove	50.0	100.0	3.00	.29
Clean brush with fingertips	16.7	91.7	9.35**	.51
Brush reusable parts	16.7	95.8	10.03**	.53
Brush channel openings of reusable parts	0.0	41.7	7.50	.46
Clean brush with fingertips or dispose of brushes	16.7	95.8	10.03**	.53
Depress pistons of each reusable part	8.3	79.2	10.32	.54

* $p < .05$. ** $p < .01$.

TABLE 6: Mean Completion Time (and *SD*) in Minutes

Task	Control		Experimental		t test	df
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>		
Leak testing	12.8	3.6	6.7	2.2	5.49**	15
Brushing	25.0	9.4	16.2	4.3	3.09**	13
Flushing	22.8	5.5	16.2	4.8	3.55**	20
Total	60.6	14.2	39.0	8.3	4.85**	15

** $p < .01$.

they reprocessed an endoscope when compared with manufacturer-provided instructions. By making the specifics of a task more visible, limiting

the number of items a user must remember, and providing feedback, the aids accommodated more effectively the participants' physical and cognitive

TABLE 7: Mean Responses (and *SD*) to Posttest Questionnaire Agreement Statements

Statement	Control		Experimental		<i>t</i> test	<i>df</i>
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>		
Reprocessing an endoscope was a physically challenging task.	2.8	1.1	2.1	1.1	1.82	21
I feel that the endoscope I reprocessed is clean enough to be used on a patient without further cleaning.	1.4	0.7	2.6	1.3	3.72**	34
Reprocessing an endoscope involved a lot of things to remember.	4.7	0.5	3.8	1.1	3.16**	34
Without the posters, the reprocessing task would have been more difficult.	4.5	0.7	4.7	0.6	0.90	21
If asked to reprocess another endoscope, I believe I could do it without referring to the written instructions.	1.6	1.2	2.4	1.5	1.76	27

Note. Scale range: 1 = *strongly disagree* to 5 = *strongly agree*.

***p* < .01.

needs during the reprocessing tasks studied. Participants in the experimental condition completed more than 87% of the reprocessing task correctly, compared to less than 45% in the control condition. Experimental participants were also significantly faster than control participants.

Static instructional aids in a poster format, however, have drawbacks. First and logistically most important is the number of slides necessary for an entire complex reprocessing procedure: anywhere between 60 and 160 slides or 4 to 8 posters. In a reprocessing area that is often smaller than a child's bedroom, having that many posters is not an option. Another concern is that although these instructional aids worked well for naïve users, they may be too detailed and ultimately ignored by experienced technicians who reprocess 20, 30, or even 40 scopes in a day. Furthermore, most reprocessing technicians are required to have up-to-date certification in the cleaning of at least several types of scopes. An aid that applies to only one type of endoscope may not be particularly useful in the reprocessing of other models, and the typically constrained workspace prevents posting of adequately detailed aids for all endoscopes a

technician will need to reprocess. Finally, when categorizing the improved tasks into the common error themes, we found that the aids were best at increasing visibility and reducing memory demands and somewhat less likely to provide better feedback. This is not surprising since many types of feedback are auditory or tactile and thus not supported in a poster. To summarize, instructional aids in a poster format are not a practical or complete solution. However, the results of this study provide a proof of concept for extension of this work. We postulate that future implementations of instructional aids in an interactive electronic format can accommodate multiple experience levels, meet display real estate constraints, and provide better feedback.

Some errors, however, are impossible to eliminate entirely with an instructional tool. A number of errors occurred because of flaws that are inherent in the design of the endoscope itself. Manufacturers design endoscopes to be used by physicians to diagnose and treat medical conditions. It is important, however, that another vital component is design for maintenance: in this case reprocessing. The endoscope,

TABLE 8: Mean Responses (and *SD*) to Posttest Questionnaire Difficulty Statements

Statement	Control		Experimental		<i>t</i> test	<i>df</i>
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>		
Identifying where to attach leak tester connector on water resistant cap	2.7	1.2	2.3	1.00	0.93	18
Understanding the instructions	4.1	0.8	2.7	0.9	5.00**	23
Securing the water resistant cap	2.4	1.3	2.0	1.0	1.06	18
Moving the endoscope from one container to another	1.8	1.2	1.8	1.0	0.21	19
Identifying if scope is pressurized	3.8	1.0	2.6	1.4	2.97**	30
Knowing where to attach the connectors of the injection tube	4.1	1.1	3.0	1.1	2.85**	22
Pushing fluid through channels using the syringe	2.6	1.4	2.3	1.0	0.66	16
Identifying which channels to brush	3.4	1.3	2.5	1.3	1.88	22

Note. Scale range: 1 = very easy to 5 = very difficult.

***p* < .01.

a tool often used and reprocessed many times a day, needs to be easy to maintain. More generally, if endoscopes are representative of other types of complex RME, this study suggests that manufacturers need to dedicate more human factors engineering resources, especially early in product development, to design for reprocessing and maintenance (Weinger, Wiklund, & Gardner-Bonneau, 2011).

This study has limitations. Because we used participants naïve to the procedure, they may have relied solely on the support materials we presented to them. This may be less authentic than real-life situations, in which an expert would train a beginner. We also assumed that the reprocessing technician was completing the procedure manually as opposed to using an automatic endoscope reprocessing (AER) unit to flush the endoscope. Although a number of

facilities use AER units, the procedure for connecting the AER to the endoscope is similar to that for attaching the injection tube, which is one of the most critical and apparently problematic steps (e.g., less than 5% of the control group successfully completed this task).

We studied only three endoscope reprocessing tasks: leak testing, brushing, and flushing. Pre-cleaning and high-level disinfection and the equipment used for those procedures should be addressed in future research. We anticipate that the human factors design elements utilized to create the instructional aids would be transferred to an electronic system in the reprocessing area that expert technicians were able to use on a regular basis. However, this system would be most effective if human factors principles were applied in the redesign of the endoscope and its reprocessing tools, a topic open for future research.

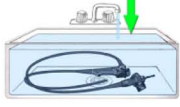
APPENDIX

Instructional Aid Used for Leak Testing

LEAK TESTING


1

Fill to line




Fill a sink to the line with warm water (4 gallons).

2



Attach the water resistant cap (MH-443) to the endoscope.


3



Insert the leakage tester connector into the MU-1.

4


Turn ON



Turn on the MU-1.

5


Push pin



Check that air is being emitted from the leakage tester connector.

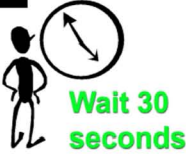
6

Note: Make sure connections are dry.



Attach the leakage tester connector cap to the endoscope.

7




Wait 30 seconds

Wait 30 seconds for the endoscope to pressurize.



8

Bend distal tip



Fully submerge endoscope. Bend distal tip back and forth using hand controls.


9

NO LEAK	LEAK
 (few or no bubbles)	 (continuous stream of bubbles)
Continue to step 10	Continue to step 24

Observe the endoscope for 30 seconds to determine if there is a leak.


10

Turn OFF



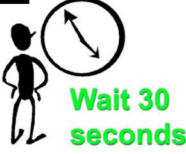
Turn off the MU-1.

11



Detach the leakage tester connector from the MU-1.


12



Wait 30 seconds

Wait 30 seconds for the endoscope to depressurize.


13



Detach the leakage tester connector from the endoscope.

14

Dry



Dry the leakage tester connector cap.

KEY POINTS

- Participants successfully completed 87.1% of the reprocessing procedure in the experimental condition as opposed to 44.7% in the control condition.
- Of 60 subtasks, 27 showed significant improvements in completion rates.
- All tasks were completed significantly faster ($p < .01$).
- Instructional aids designed with human factors principles facilitated more successful and therefore more safe reprocessing.

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