Research, Design and Validation of a Cognitive Aid to Support the Reprocessing of Flexible Endoscopes

by

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ABSTRACT

The objective of this project was to evaluate human factors based cognitive aids on endoscope reprocessing. The project stems from recent failures in reprocessing (cleaning) endoscopes, contributing to the spread of harmful bacterial and viral agents between patients. Three themes were found to represent a majority of problems: 1) lack of visibility (parts and tools were difficult to identify), 2) high memory demands, and 3) insufficient user feedback. In an effort to improve completion rate and eliminate error, cognitive aids were designed utilizing human factors principles that would replace existing manufacturer visual aids. Then, a usability test was conducted, which compared the endoscope reprocessing performance of novices using the standard manufacturer-provided visual aids and the new cognitive aids.

Participants successfully completed 87.1% of the reprocessing procedure in the experimental condition with the use of the cognitive aids, compared to 46.3% in the control condition using only existing support materials. Twenty-five of sixty subtasks showed significant improvement in completion rates.

When given a cognitive 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 patient use.

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INTRODUCTION

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

Contaminated endoscopes generally result from incomplete or improper disinfection or reprocessing practices, a subject that has recently gained media attention and has piqued public concern for patient safety. Because endoscopes are inserted into the body and are often used on multiple patients each day, they risk 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 endoscopes more difficult to reprocess than many other types of reusable medical equipment (Ninemeier, 2003). In one study, nearly 24% of the bacterial cultures from the internal channels of 71 gastrointestinal endoscopes grew significant colonies of bacteria after completion of all reprocessing procedures (Rutala et al., 2008). This could be due to leftover contaminating organisms, or bioburden, which often remain after reprocessing (Ishino, Ido, Koiwai, 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, between patients (Weber & Rutala, 2001; Mehta et al., 2006) resulting in, at minimum, a drastic lifestyle change and at worst death. To reduce the possibility of outbreaks due to contaminated endoscopes, it is imperative to identify problem areas within current reprocessing practices and develop, evaluate, and implement evidence-based solutions. This thesis discusses those problem areas, human factors principles for reducing those problems, how we applied the principles to the design of a cognitive aid, how we tested the validity of 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).

LITERATURE REVIEW

Reprocessing

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

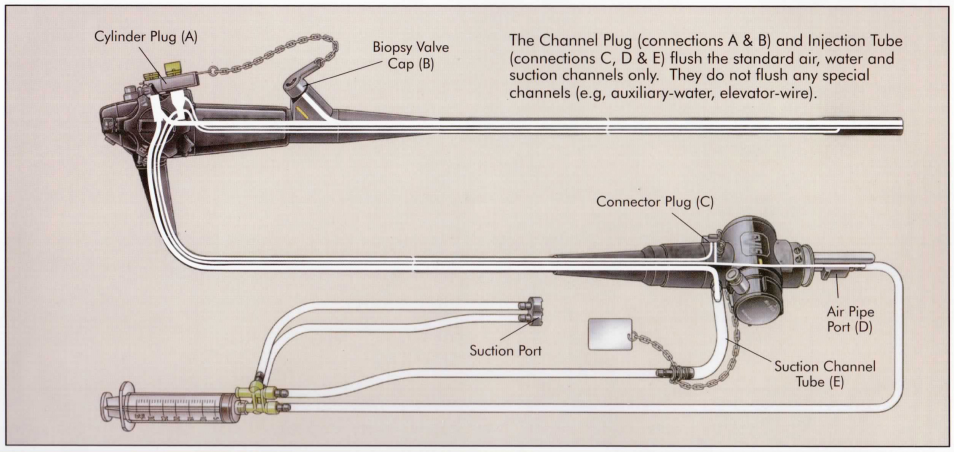

Figure 1. Olympus manufacturer flexible endoscope and reprocessing equipment.

Reprocessing procedures typically include the following sequential subtasks: pre-cleaning, leak testing, cleaning, disinfecting, sterilization, rinsing, drying, and storage (Rutala & Weber, 2004). The cleaning portion of the reprocessing 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, briefly described below, summarize what is often a 75-page manufacturer's instruction manual or a 30-page standard operating procedure (SOP).

- Pre-cleaning: Completed bedside immediately following patient procedure. Suction detergent through all endoscope channels and flush with water. Remove valves and removable parts and soak in detergent solution. Transport all equipment to the reprocessing area.

- Leak testing: connect the scope to an air source and submerge it in clean water to check for a continuous stream of air bubbles, which indicate damage to the scope.
- Cleaning: mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with an enzymatic cleaner and water.
- Disinfection: immerse the endoscope in high-level disinfectant and perfuse disinfectant into all accessible channels and expose for a recommended amount of time. High-level disinfection eliminates most pathogenic microorganisms, except bacterial spores, on inanimate objects. This is usually accomplished by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of disinfection can nullify or limit the efficacy of the process. Unlike sterilization, disinfection does not necessarily kill spores. Twenty minutes for 2% glutaraldehyde, will kill all microorganisms except large numbers of bacterial spores.
- Sterilization: sterilization destroys or eliminates microbes and is carried out using pressurized steam, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, and liquid chemicals.
- Rinsing: 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 after disinfection and before storage.

- Storage: store the endoscope in a way that prevents recontamination and promotes drying (e.g., hung vertically).

The reprocessing procedure is time consuming, physically engaging, and cognitively demanding. A given hospital may have several different models of endoscopes for gastroenterology (GI) procedures, in addition to bronchoscopes, laparoscopes, cystoscopes, arthroscopes, and others. Each has its own reprocessing method, instructions, and SOPs. A reprocessing technician will need to identify each type, make, and model, and apply the appropriate procedures in a busied environment. Further, depending on the healthcare facility, an individual reprocessing technician could reprocess as many as 40 endoscopes per day, each requiring up to 40 minutes to complete (multiple endoscopes may be in various stages of reprocessing at once).

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) as shown in Table 1. This study suggests

that the current reprocessing procedures and device design are problematic and needed to be investigated further.

Table 1

Description of Top Three Violations in Hildebrand et al. (2010)

Heuristic	Description	Percentage of violations
Error	It's better to design interfaces that prevent errors from happening in the first place.	44.40%
Memory	Users shouldn't be required to memorize a lot of information. Memory load reduces user's capacity to carry out the tasks.	18.77%
Feedback	Users should be given prompt and informative feedback about their actions.	12.64%

Next, Jolly et al. (in-press) conducted a study investigating the success rate of naïve users when reprocessing endoscopes. Users were tasked with simulating the reprocessing of an endoscope, with the equipment and support materials commonly available to reprocessing technicians. The materials included the standard operating procedures (SOPs) and manufacturer visual aids. Naïve participants were tested for several reasons. First, hospital facilities 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 so we could identify the most confusing problems. Third, although it is common for reprocessing technicians to receive some type of one-on-one training for endoscope reprocessing 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, filling the role of a reprocessing technician. Though she had received an orientation to endoscope reprocessing (Department of Veterans Affairs Office of Inspector General, 2009), she was observed improperly reprocessing a specific type of endoscope 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 visual aids as they saw fit. The results were disastrous: 0 of 24 participants were able to successfully reprocess an endoscope using only the support materials and on average, fewer than half of the required subtasks of the procedure were completed free of error. Of the 76 subtasks tested, five were identified as being particularly critical, based on 1) the number of participants who failed to correctly complete the subtask, 2) how that failure affected subsequent subtasks in the procedure, 3) how representative the subtask was of the task as a whole, and 4) potential risk of infection. Table 2 summarizes these critical subtasks and identifies potential consequences as a result of their incompletion.

Table 2

Five Critical Subtasks of Reprocessing in Jolly et al. (in-press)

Task	Result/Potential Consequence	Mean Percent Error Free Completion
Brush instrument channel	Channel not completely brushed/ Remaining bioburden	4.20%
Attach channel plug/ injection tube	Channels not completely flushed/ Remaining bioburden or detergent	4.20%
Observing scope for leak	Incomplete leak detection/ Costly damage to scope	16.70%
Drying	Channels left moist/ Bacterial or viral growth in internal channels	25.00%
Suctioning detergent	Channels not completely flushed/ Remaining bioburden	45.80%

The source of error for each of these critical subtasks, as well as the majority of problems in the reprocessing procedure, fell into three common themes, which are described below: 1) lack of visibility, 2) high memory demands, and 3) insufficient feedback.

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 a number of errors due to 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.

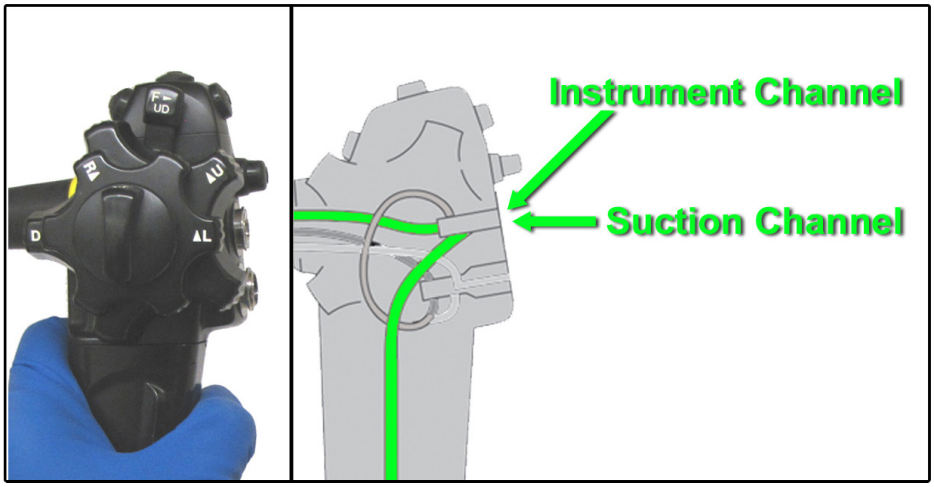

Figure 2. Flexible endoscope with multiple channels accessed via a single port.

High Memory Demands. Reprocessing currently involves dozens of parts, conflicting visual aids located separately from the SOPs, and over two hundred sequential steps. The sheer volume of materials and steps alone are enough to tax memory, especially if a user were interrupted. Additionally, the names of parts and tools, as well as part numbers, are long and too 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. This caused confusion and contributed to error.

Feedback. Without cues signaling the successful completion of a step, participants were frequently 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 specifically reference any

manufacturer 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.

Errors associated with each of these themes involve the endoscope itself, reprocessing tools, and the support materials (e.g. the SOPs and manufacturer visual aids). For this study, we focused on the development and evaluation of design elements of the support materials that can be modified to help increase visibility, lower memory demands, and provide better feedback. One may question why our focus lies on creating user-friendly instructions for a set of user unfriendly tools instead of simply redesigning the endoscope and its components. Currently we have little control of the manufacturer design of the endoscope and reprocessing tools. To make a positive impact in patient safety in the short term, we chose to revamp the support materials first. Our long term goal is, however, to affect endoscope redesign in a way that makes them easier to reprocess which in turn will make them safer for the patient.

Basis for Cognitive Aid Design

Norman (1993) stated that "the power of the unaided mind is highly overrated". He emphasized that without external aids, our memory, thought, and reasoning are highly constrained. When well-designed, external aids (such as the endoscope reprocessing support materials) can complement our abilities, strengthen our mental powers, and help us overcome our own limits. However, in the case of endoscope reprocessing, poorly-designed support materials consistently contributed to improperly cleaned endoscopes that had the potential to spread infection between patients.

To discover what specifically contributed to this poor design, we examined the existing support materials further and discovered that the SOPs often failed to correspond accurately with the manufacturer visual aids (on occasion completely contradicting them) and lacked easy to understand instructions. This might be expected, given that individuals without technical writing expertise wrote them. SOPs are typically written to fulfill an organizational requirement rather than to provide utility to technicians. Further, the frequency of use and availability of the SOPs varies 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 tend to oversimplify the reprocessing 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 is issued on the manufacturer visual aids stating that they are incomplete and that technicians should reference the manufacturer instruction manual. Unfortunately, these manuals are not always located in the reprocessing area (Figure 4).

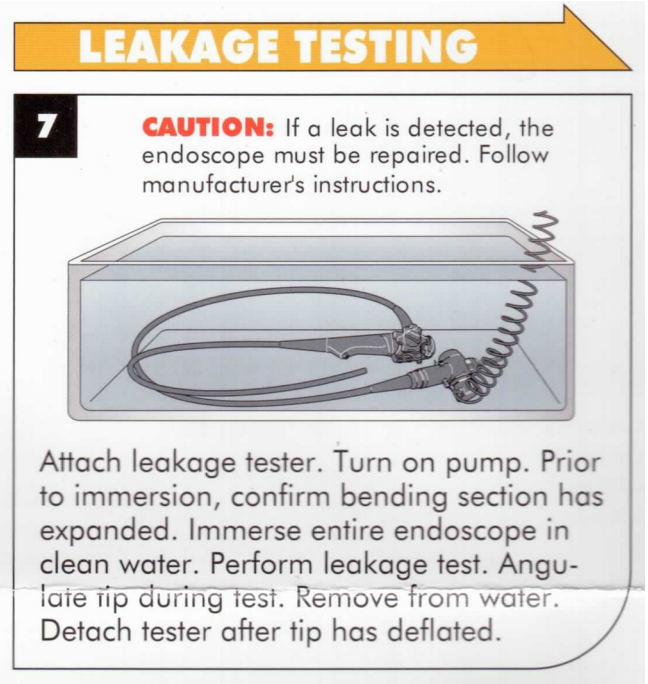

Figure 3. Olympus manufacturer slide for leak testing.

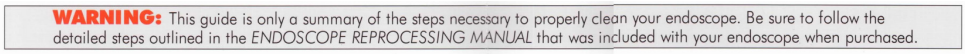

Figure 4. Olympus manufacturer warning.

Our evaluation of the support materials revealed many opportunities for redesign that could lead to improved comprehension and ultimately safer endoscope reprocessing. As a result, the goal of this study was to create a cognitive aid that could be used safely and effectively for the reprocessing of flexible endoscopes.

Cognitive Aid Development

To begin the design process, hypothesized that the cognitive aids should be able to effectively guide a novice user through the entire reprocessing procedure (no need to reference SOPs or to ask for help). This would simulate a

real life situation in which a new reprocessing technician was left alone or needed to reprocess a scope they had not yet seen, but had no one else with whom to consult. We chose a poster format for the cognitive aids and to account for space constraints in an actual reprocessing room, we limited them to fewer than 20 slides each. To better understand the reprocessing procedure we gained hands on knowledge of endoscope reprocessing by being trained personally by multiple reprocessing experts at several hospitals. Due to time constraints and availability of equipment, we decided to create cognitive aids for only the leak testing and manual cleaning (brushing and flushing) portions of reprocessing as a proof of concept (this omits the high level disinfection task).

To focus the direction of the cognitive aids, we used our training experience, the manufacturer instructions and posters, the SOPs, and our knowledge of human factors principles to identify which and how cognitive tasks in the reprocessing procedure might best be supported by design. The design process was iterative, taking many sessions to produce a product that was ready to test. When creating the cognitive aids we utilized a number of different 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 3 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.

Table 3

Design Principles Emphasized in Cognitive Aid Creation

Design Principle	Purpose
Orientation	Endoscope and tools were shown in a first person point of view to limit the need for mental rotation.
Consistency	Green text and arrows were used consistently for visual instructions.
Color Coding	Each of the three tasks (leak testing, brushing, and flushing) was color coded to emphasize the difference in tasks and relation of subtasks.
Color Blindness Accommodation	8% of males are missing red/green channels and have difficulty distinguishing between the two. Colors were chosen to be salient and all instructions were dual-coded with text.
Visual Guidance	Aspects of images were enhanced or suppressed to direct the user to what they needed to see or understand.
Pictures & Words	Visual and language modalities were combined in close proximity to allow cognition to be most effective.
Discrimination	Visuals were created to help users find similar parts or tools without needing to know the name or part number.
Unity	Automaticity was maximized with familiar fonts, absence of abbreviations, and lowercase letters.
Vocabulary	Confusing vocabulary was eliminated and sentence structure adjusted to limit perceptual errors under stress.
Simplicity	Slides were kept simple to accommodate working memory restrictions.
Knowledge in the World	Information (knowledge) was put into the cognitive aids (the world) to limit user memory demand.

Increasing visibility. Following the principle of consistency (Nielsen, 1994), green text and arrows were used to express primary instructions the same way throughout the cognitive aids. By creating a consistent visual design, users are able to more 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 eight percent of males are missing red-green channels and have trouble distinguishing between red and green (Ware, 2008), we used color combinations that were salient and dual-coded all instructions (visuals and text) to accommodate those with this most common form of color-blindness. Often, human visual sensory performance relies on the ability to discriminate between two or more signals rather than to detect or identify any one signal (Wickens et al. 2004). As such, the visuals were designed to allow users to easily discriminate between different tools and areas of the endoscope without having to identify an item by part name or number. We did this by enhancing or suppressing different aspects of images to better direct the user to the needed item or tool, making the name or part number less relevant in completing the task. Instructions for the picture seen in Figure 5 would have been "Remove the suction valve (MH-443) from the suction port of the endoscope and place it in the sink," which would be more difficult to understand without a picture and would require identifying the valve and port separately.

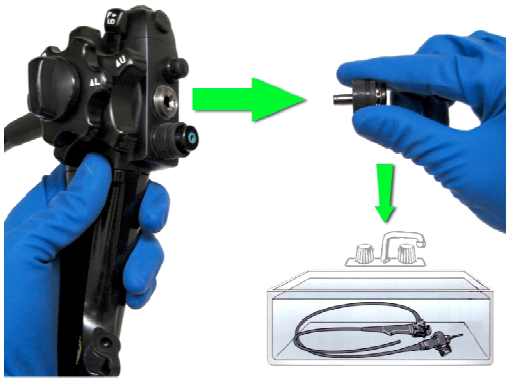

Figure 5. Suction valve removal.

Reducing Memory Demands. To create an effective cognitive aid, 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 cognitive aids display the endoscope and its tools in a first person point-of-view which reduces the user's need for mental rotation. We also maximized automaticity and unitization by using a common font, Arial, throughout the cognitive aids, as well as using lowercase font and complete words rather than abbreviations (Wickens, 2004). The vocabulary was designed to be remembered more easily by removing confusing terms and limiting technical jargon. For example, the SOPs refer to two brushes that are needed when reprocessing an endoscope: the channel cleaning brush and the channel opening cleaning brush, also called the valve/head brush. The new cognitive 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 (see Figure 6). In addition, vocabulary was changed to decrease perceptual errors under stress (e.g. "Do not put push the brush in completely" could be read as "Push the brush in completely"). 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."

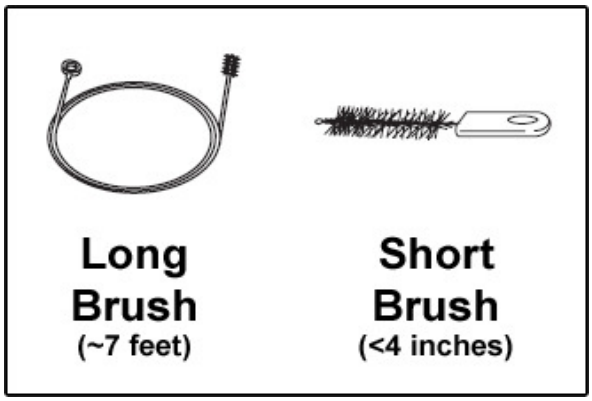

Figure 6. Long brush versus short brush.

Providing Sufficient Feedback. The cognitive aids provide visual feedback of how a part or tool should look when attached properly as well as alerting the user of auditory feedback to expect, where applicable. One example of this is the visual displaying an audio signal that users should hear when the endoscope is properly depressurized (Figure 7).

Figure 7. Endoscope being properly depressurized.

PURPOSE

The purpose of this study was to evaluate the efficacy of the newly developed cognitive aids. Since the brain is most effective when visual and language modalities are combined (Ware, 2008), the SOPs and posters were combined and improved to create an aid that could be used safely and effectively for the reprocessing of flexible endoscopes. The cognitive aids have been designed following human factors principles, specifically focusing on remedying the three main error themes found in our previous study (Jolly et al., in-press): 1) lack of visibility, 2) high memory demands, and 3) insufficient user feedback.

HYPOTHESIS

With the use of the new cognitive aids, participants will complete the reprocessing task more safely and efficiently than when using the previous support materials (SOPs and manufacturer visual aids). Specifically, the use of the cognitive aids will significantly reduce errors and decrease the overall time to complete.

METHOD

Participants

Thirty-six students, (20 male, 16 female) between the ages of 18 and 54, participated in this experiment for credit in psychology classes at a large university in the southwestern United States. Participants had no experience in reprocessing endoscopes, simulating a real life situation in which a new reprocessing technician was left alone or needed to reprocess a scope they had not

yet seen. Demographic data including age, educational background, reprocessing experience, and sex were recorded.

Test Sites

Usability testing occurred at the Human Interaction and Technology (HIT) Lab, Applied Psychology Department, at a large university in the southwestern United States.

Materials

This study was conducted in a simulated reprocessing lab at the test site noted above. The following materials were visibly available to the participants at the beginning of the session:

- Standard Operating Procedures (SOPs) for endoscope reprocessing from a Veterans Health Affairs hospital
- Personal Protective Equipment (PPE)
- Olympus GIF H160 Endoscope
- Suction Valve (MH-443)
- Air/Water Valve (MH-438)
- Red Contaminated Transport Container
- Lint-Free Cloths
- Prolystica Enzymatic Cleaner & Pump
- Sink (clear container used as substitute)
- Water Resistant Cap (MH-553)
- MU-1 Leak Tester
- Leakage Tester Connector

- Lint-Free Towels
- Air Tube
- Disposable Channel Brush (BW-201T)
- Disposable Valve/Control Head Brush (MAJ-1339)
- Suction Tube
- Suction Cleaning Adapter (MH-856)
- 30 ml Syringe
- Channel Plug w/ Instrument Port Cap (MH-944)
- Injection Tube (MH-946)
- PCS 414 Air Compressor
- Manufacturer Visual Aids
- Revised Cognitive Aids

Procedure

There were two conditions: the control, where participants were to complete the reprocessing of an endoscope using the manufacturer visual aids and the experimental, where the manufacturer visual aids were replaced with the new cognitive aids. Participants were randomly assigned to each condition, 12 for the control and 24 for the experimental.

In both conditions participants were run individually. The experimenter greeted the participant and made him or her comfortable. Each participant signed a copy of the informed consent and release to photograph form prior to beginning the study. They were also given a copy of the form to keep for their personal

records. All signed informed consent forms are kept in a locked cabinet in a lab, which allows only authorized access.

Participants then watched a short video consisting of clips from a Veterans Health Affairs (VHA) orientation video for new reprocessing technicians that introduces them to endoscopes and the reprocessing procedure. The video was seven minutes in duration and was used to simulate a brief orientation that an expert might give to a new or acting reprocessing technician. This was followed by a short background questionnaire.

Next, participants were provided with all the necessary directions and materials to complete a given scenario that resulted in them reprocessing an endoscope as if working independently. In the control condition materials included the manufacturer visual aids, whereas in the experimental condition, these were replaced by the new cognitive aids. Time to complete each subtask, errors (deviations made from the instructions), and requests for assistance were recorded by the experimenter. 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 compensated the participant for his or her time in the form of educational credit.

Analysis

The analyses reported below compare the control group with the experimental group. Between group differences of numbers of tasks completed successfully and self-efficacy ratings were analyzed for statistical significance using independent sample t-tests and individual task completion rate was analyzed using Chi-square.

RESULTS

For analysis we divided the reprocessing procedure into three tasks: 1) leak testing, 2) brushing, and 3) flushing. Of particular interest is that 25 of the 60 subtasks tested were completed with significantly fewer errors. Further, on average, participants were able to complete 87.1 % of the 60 subtasks free of error in the experimental condition, as opposed to 46.3% in the control condition.

Completion Rate

As illustrated in Table 4, for each of the three reprocessing tasks, the experimental group showed a higher rate of successful completion than control. This supports the hypothesis that cognitive aids designed with human factors principles significantly reduce errors.

Table 4

Mean Successful Completion Rates (SD) for the Three Reprocessing Tasks

Task	Control % (SD)	Experimental % (SD)	*t*-test
Leak Testing	72.94 (16.93)	85.94 (8.69)	2.505*
Brushing	33.32 (20.49)	87.16 (12.92)	8.312**
Flushing	35.95 (21.51)	87.95 (11.58)	7.825**
Total	44.72 (17.05)	87.08 (8.50)	8.115**

Note. *p<.05, **p<.01

Of the five critical subtasks identified in Jolly et al. (in-press), three were tested here. Criticality was determined by 1) the number of participants who failed to correctly complete a subtask, 2) how that failure affected other subtasks in the procedure, 3) how representative the subtask was of the task as a whole, and 4) potential risk for infection. All three showed significant improvements in rate of successful completion in the experimental condition (Table 5).

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 observing an endoscope for a leak, participants should keep the endoscope completely submersed in water and use the hand controls to bend the distal tip while looking for a continuous stream of bubbles. Participants having trouble with this step in the experimental condition often

failed to identify the distal tip or did not understand the importance of keeping the endoscope fully submersed. Even with multiple iterations of the cognitive aids with special attention paid to this step, vital pieces of information were not adequately conveyed. This illustrates the need for testing and revising any instructional materials used in a sensitive task such as endoscope reprocessing.

Table 5

Successful Completion Rates for Three Critical Subtasks

Subtask	Control (%)	Experimental (%)	χ^2
Observe endoscope for leaks	0.00	58.33	10.50**
Insert brush into instrument channel	33.33	91.67	4.90*
Attach the channel plug and injection tube	0.00	91.67	16.50**

Note. *p<.05, **p<.01

Tables 6-8 compare completion rates for each of 60 individual subtasks. Table 6 reports rates for leak testing, Table 7 for brushing, and Table 8 for flushing. The experimental condition showed significantly better rates of completion in 27 of the 60 subtasks. The control condition was not significantly superior in any of the tasks.

Table 6

Successful Completion Rates for the Subtasks in Leak Testing

Subtask	Control (%)	Experimental (%)	χ^2
Secure water resistant cap	100.00	95.83	.02
Insert leakage tester connector into leak testing unit	100.00	95.83	.02
Turn on leak tester	100.00	100.00	.00
Confirm leak tester is emitting air	58.33	95.83	1.64
Confirm leak tester's connector cap is dry	33.33	45.83	.36
Confirm water resistant cap's venting connector is dry	25.00	45.83	1.10
Attach leak tester connector to cap venting connector	91.67	100.00	.07
Verify pressurization	75.00	100.00	.64
Immerse endoscope	83.33	87.50	.02
Observe endoscope for leaks	0.00	58.33	10.50**
Identify that no leak is present	100.00	95.83	.02
Turn off leak tester	100.00	100.00	.00
Disconnect leak tester connector from leak tester	66.67	58.33	.10
Wait for endoscope to depressurize	91.67	100.00	.07
Disconnect leakage tester connector from endoscope	100.00	100.00	.00
Dry the leakage tester connector cap	41.67	95.83	3.84*

Note. *p<.05, **p<.01

Table 7

Successful Completion Rates for Subtasks in Brushing

Subtask	Control (%)	Experimental (%)	χ^2
Confirm addition of enzymatic cleaner	41.67	91.67	3.38
Remove and immerse reusable parts	16.67	95.83	10.03**
Set scope to free position	0.00	95.83	17.25**
Wipe exterior of endoscope (keep immersed)	58.33	75.00	.38
Straighten endoscope bending section	8.33	95.83	13.23**
Insert brush into instrument channel	33.33	91.67	4.90*
Push brush through channel	33.33	91.67	4.90*
Clean brush with fingertips	33.33	91.67	4.90*
Remove brush correctly	8.33	83.33	11.05**
Clean brush with fingertips	8.33	70.83	8.88**
Insert brush into suction channel	75.00	100.00	.64
Push brush through channel	75.00	100.00	.64
Clean brush with fingertips	41.67	95.83	3.84*
Remove brush correctly	50.00	87.50	1.84
Clean brush with fingertips	33.33	83.33	3.86*
Brush suction cylinder	58.33	62.50	.03
Turn brush and remove	66.67	87.50	.51
Clean brush with fingertips	25.00	79.17	5.07*
Brush instrument channel port	58.33	95.83	1.64
Turn brush and remove	50.00	100.00	3.00
Clean brush with fingertips	16.67	91.67	9.35**
Brush reusable parts	16.67	95.83	10.03**
Brush channel openings of reusable parts	0.00	41.67	7.50
Clean brush with fingertips or dispose of brushes	16.67	95.83	10.03**
Depress pistons of each reusable part	8.33	79.17	10.32

Note. *p<.05, **p<.01

Table 8

Successful Completion Rates for Subtasks in Flushing

Subtask	Control (%)	Experimental (%)	χ^2
Immerse channel plug and injection tube	41.67	79.17	2.10
Attach the channel plug (metal portion)	25.00	91.67	6.86**
Attach the channel plug (rubber portion)	25.00	100.00	8.10**
Attach the injection tube (suction tube)	66.67	100.00	1.20
Attach the injection tube (air/water plug)	58.33	100.00	1.97
Attach the injection tube (air tube)	50.00	100.00	3.00
Suction port of the injection tube is immersed	100.00	100.00	0.00
Flush solution through the air/water channel	16.67	91.67	9.35**
Flush solution through the suction channel	16.67	91.67	9.35**
Transfer scope and all equipment to container	41.67	100.00	4.32*
Agitate scope and parts	25.00	75.00	4.50*
Depress pistons of each valve	16.67	91.67	9.35*
Flush water through the air/water channel	16.67	91.67	9.35*
Flush water through the suction channel	16.67	87.50	8.67**
Transfer scope and all equipment to towel	75.00	100.00	.64
Cover distal end and control section with cloth	8.33	33.33	2.70
Flush air through the air/water channel	16.67	87.50	8.67**
Flush air through the suction channel	16.67	83.33	8.00**
Detach all reprocessing equipment	50.00	66.67	.43

Note. *p<.05, **p<.01

Post-test Questionnaire

Participants rated their agreement with the following statements using a scale ranging from 1 = strongly disagree to 5 = strongly agree (Table 9). The results, shown in Table 9, suggest that participants in the experimental group felt more confident that they successfully reprocessed the endoscope and believed there were less memory demands than did controls. All other comparisons were not significant.

Table 9

Mean Responses (SD) to Post-Test Questionnaire Agreement Statements

Statement	Control (SD)	Experimental (SD)	*t*-test (p)
Reprocessing an endoscope was a physically challenging task.	2.83 (1.12)	2.13 (1.08)	1.82 (.078)
I feel that the endoscope I reprocessed is clean enough to be used on a patient without further cleaning.	1.42 (.67)	2.63 (1.28)	3.72 (.001)**
Reprocessing an endoscope involved a lot of things to remember.	4.67 (.49)	3.83 (1.09)	3.16 (.003)**
Without the posters, the reprocessing task would have been more difficult.	4.50 (.67)	4.71 (.62)	.90 (.377)
If asked to reprocess another endoscope, I believe I could do it without referring to the written instructions.	1.58 (1.17)	2.38 (1.47)	1.76 (.089)

Note. *p<.05, **p<.01, scale range: 1 = strongly disagree to 5 = strongly agree

Participants also rated the ease or difficulty of the following steps on a scale of 1 = very easy to 5 = very difficult (Table 10). Interestingly, the participants in the experimental condition rated the difficulty of all the steps in

Table 10 as less difficult, a trend that makes sense with the significant improvement in performance. Rated as substantially easier were: understanding the instructions, knowing where to attach the connectors of the injection tube, and identifying if the scope was pressurized.

Table 10

Mean Responses (SD) to Post-Test Questionnaire Difficulty Statements

Statement	Control (SD)	Experimental (SD)	*t*-test (p)
Identifying where to attach leak tester connector on water resistant cap.	2.67 (1.23)	2.29 (.96)	.93 (.361)
Understanding the instructions.	4.08 (0.79)	2.67 (.87)	5.00 (<.001)**
Securing the water resistant cap.	2.42 (1.31)	1.96 (1.04)	1.06 (.298)
Moving the endoscope from one container to another.	1.83 (1.19)	1.75 (.99)	.21 (.836)
Identifying if scope is pressurized	3.75 (.97)	2.58 (1.35)	2.978 (.005)**
Knowing where to attach the connectors of the injection tube.	4.08 (1.08)	3.00 (1.06)	2.85 (.007)**
Pushing fluid through channels using the syringe.	2.58 (1.38)	2.29 (.96)	.66 (.515)
Identifying which channels to brush.	3.42 (1.31)	2.54 (1.32)	1.88 (.068)

Note. *p<.05, **p<.01, scale range: 1 = very easy to 5 = very difficult

Preferred Training Method

Participants were asked to rank the effectiveness of the following possible forms of training for reprocessing an endoscope shown in Table 11 on a scale of 1 = most effective to 5 = least effective. Not surprisingly, one-on-one training was ranked the most effective for both conditions. In the experimental condition,

posters were ranked significantly more effective than in the control. This suggests participants ranked the effectiveness of the posters based on their most recent experience: more effective for the cognitive aids and less effective for the manufacturer visual aids.

Table 11

Preferred Training Method

Training Method	Control (SD)	Experimental (SD)	*t*-test (p)
Step-by-step audio instructions	4.33 (.49)	4.38 (1.01)	.17 (.869)
Step-by-step written instructions	4.25 (1.06)	3.92 (.97)	.92 (.366)
One-on-one training	1.33 (.65)	1.42 (.72)	.35 (.729)
Step-by-step instructional posters	3.08 (.79)	2.50 (.72)	2.14 (.039)*
Animated play as you go video tutorial with step-by-step instructions	2.00 (.78)	2.79 (1.29)	2.20 (.034)*

Note. *p<.05, **p<.01, ranking: 1 = most preferred to 5 = least preferred

Completion Time

In all measured tasks, the experimental group conducted all tasks significantly faster than the control group (Table 12).

Table 12

Mean (SD) Completion Time in Minutes

Task	Control (SD)	Experimental (SD)	*t*-test (p)
Leak Testing	12.83 (3.56)	6.67 (2.22)	5.49 (<.001)**
Brushing	25.00 (9.39)	16.21 (4.28)	3.09 (.004)**
Flushing	22.75 (5.45)	16.17 (4.82)	3.55 (.001)**
Total	60.58 (14.24)	39.04 (8.29)	4.85 (<.001)**

Note. *p<.05, **p<.01

DISCUSSION

Endoscopes are valuable medical tools that have revolutionized diagnostic and surgical procedures for a variety of medical disorders. Because of the effectiveness of endoscopy and its minimally invasive nature, there are approximately 15 million GI endoscopies completely annually (Humphrey & Kovach, 2006). Although a majority of these procedures are completed with adequately reprocessed endoscopes, there are more healthcare-associated outbreaks linked to contaminated endoscopes than any other medical device (Rutala & Weber, 2004). Endoscope reprocessing includes cleaning, decontamination, and high-level disinfection and sterilization to ensure an endoscope is safe for re-use. Each type of endoscope has a unique procedure involving hundreds of sequential steps using dozens of components. Reprocessing technicians are required to complete these in a busied environment with few or no instructional tools to guide them. To reduce the possibility of outbreaks due to improperly reprocessed, contaminated endoscopes, this study has identified problem areas within current reprocessing practices and has developed and evaluated a potential evidence-based solution.

The human factors based cognitive aids tested in this study provided the reprocessing user with all of the necessary information to reprocess an endoscope, although, in a more understandable format than previously available. The aids were created by applying design principles primarily associated with increasing visibility, reducing memory demands, and improving feedback: three common error themes found to be associated to endoscope reprocessing (Jolly et al., in-

press). Indirectly, each of these design principles acknowledges the notion that humans inevitably err. By making the specifics of a task more visible, limiting the number of items a user must remember, and providing feedback showing the user they have completed a task correctly, the aids accommodate the physical and mental limitations that humans inherently possess. Participants in the experimental condition completed over 87% of the reprocessing task correctly, compared to less than 47% in the control condition. Participants were also significantly faster with the use of the cognitive aids.

Worth noting is the need to iterate design solutions. This entails numerous revisions, informed by usability testing, and empirical data. This seems particularly apropos in the medical industry. For example, despite the numerous iterations of these aids by a group of skilled, human factors professionals, several faults made it through to testing. These affected the user's comprehension of the instructions, thus adding to their error.

Another concern is that, though these cognitive aids worked well for naive 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 and lack of space makes it impossible to put adequately detailed aids up for all the endoscopes a technician reprocesses. The design of human factors based cognitive aids in poster format is simply to show a proof of concept: that an instructional device in this situation should be

able to effectively guide a user through the entire procedure. We anticipate that future iterations of this design will lead to an interactive electronic-based cognitive aid that will be able to accommodate multiple levels of users in a variety of ways to positively influence the safe reprocessing of endoscopes.

Despite our best efforts to create well-designed cognitive aids, they still were unable to eliminate a number of errors because of flaws that are inherent in the design of the endoscope itself. Manufacturers design endoscopes to be used by doctors to diagnose and treat a number of medical ailments. This is important, however, another vital component to consider in this design is maintenance: in this case, reprocessing. The endoscope, a tool often used and reprocessed multiple times a day needs to be easy to maintain so that it continues to provide safe service. What can safely be said in relation to this study is that endoscopes are not designed for easy reprocessing, which takes place just as often as the primary medical uses of the endoscope, and is paramount to patient safety. Manufacturers need to consider the reprocessing technician and reprocessing procedure as important as the doctor and medical procedure when designing reusable medical equipment (RME) such as endoscopes.

Of course, there are limitations to this study. Because we are using participants naïve to the procedure, they are going to rely solely on the support materials we present to them. This may be less faithful to real-life situations in which a beginner would most likely be trained by an expert who would educate them on the specifics of endoscope reprocessing and would often be able to readily answer questions.

This study also assumes the reprocessing technician is completing the procedure manually as opposed to using an automatic endoscope reprocessing (AER) unit to flush the endoscope. Although a number of facilities use an AER unit, the procedure to connect the AER to the endoscope is a task similar to attaching the injection tube, which was one of the most problematic and critical steps found in the control group with only a 4.2% completion rate.

Also, this study tests only the leak testing and manual cleaning portions of endoscope reprocessing. Pre-cleaning and high-level disinfection steps and the equipment used for those procedures may need to be addressed in future research.

Finally, it must be noted that in general, expert reprocessing technicians often do not rely on the existing support materials available to them, so the usefulness of cognitive aids that are never referenced is questionable.

We anticipate that the human factors design elements utilized to create the cognitive aids, found to significantly reduce error, would be transferred to a viable system used on a regular basis by expert reprocessing technicians to ensure patient safety. However, this system would be most effective if human factors principles were also applied in the redesign of the endoscope and its reprocessing tools: an area open for future research.

In conclusion, participants successfully completed 87.1% of the reprocessing procedure in the experimental condition compared to 46.3% in the control condition. Twenty-five of sixty subtasks showed significant improvements in completion rates. All tasks were completed significantly faster ($p<.01$) and the three tested critical subtasks identified in Jolly et al. (in-press)

showed significant improvement in this study. Because of these findings, we have found the hypothesis to be supported, that is, cognitive aids designed with human factors principles, facilitate more successful and therefore more safe reprocessing.

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