Patient Safety and Reprocessing: A Usability Test of the Endoscope Reprocessing Procedure

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Abstract

When endoscopes are reprocessed correctly, endoscopy is a safe procedure. Recent incidents of insufficient reprocessing, however, have resulted in public concern. Results of a usability test of the reprocessing procedure identified that none of 24 users, naïve to the procedure, could reprocess endoscopes correctly, nor could they correctly complete any of the component tasks in the procedure. Five of the 76 subtasks were identified as particularly critical. These were 1) brushing the instrument channel, 2) attaching the channel plug and injection tube, 3) identifying leaks, 4) blowing water out of the endoscope's internal channels during high-level disinfection, and 5) aspirating solution through the endoscope to remove debris loosened by brushing. Additionally, three themes were identified as causes of the majority of problems: 1) lack of visibility, 2) high memory demands, and 3) insufficient user feedback. Design recommendations for these problems are discussed. © 2011 Wiley Periodicals, Inc.

Keywords: Patient safety; Reusable medical equipment; Endoscope; Reprocessing; Usability test

1. INTRODUCTION

This article reports the results of a usability test on the reprocessing of a flexible endoscope, which includes precleaning, manual cleaning, and high-level disinfection or sterilization. It identifies common usability problems associated with the procedure, commonalities among them, and potential ways of remedying these problems.

In the United States, more than 46 million surgical procedures are conducted annually, and there are even more nonsurgical invasive medical procedures (Rutala & Weber, 2004; Rutala, Weber & Healthcare Infection Control Practices Advisory Committee, 2008). Within that measure are approximately 10 million gastrointestinal (GI) endoscopies. Because it is minimally invasive, endoscopy is a highly demanded medical procedure, and has become a valuable tool to diagnose and treat numerous medical disorders. Although the incidence of infection associated with the use of endoscopes is low, there are more health care–associated outbreaks linked to contaminated endoscopes than to any other medical device (Rutala & Weber, 2004).

Indeed, transmission of infectious viruses, including Hepatitis B and Hepatitis C, has occurred through the procedural reuse of endoscopes (Mehta et al., 2006; Weber & Rutala, 2001). One study found that almost 24% of the bacterial cultures from the internal channels of 71 GI endoscopes grew substantial colonies of bacteria after completion of all disinfection and

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sterilization (Rutala et al., 2008). In January 2009, one large hospital system indicated that more than 38% of its facilities were not in compliance with the manufacturer's instructions for reprocessing endoscopes. Several recent incidents of unsound and inconsistent reprocessing practices have resulted in media attention and increased public concern for patient safety regarding the reprocessing of endoscopes and other reusable medical equipment.

Although infection prevention is integral to the patient safety movement, as evidenced in the National Patient Safety Goals by the Joint Commission released in 2009, the link between reprocessing errors and infection has received little public or scientific attention. For example, the Institute of Medicine's report '*To Err Is Human*' (Kohn, Corrigan, & Donaldson, 2000), mentioned the term "infection" only eight times, whereas "medication" was mentioned 234 times. In contrast with 70 mentions of medication errors, reprocessing error was not mentioned once in the Institute of Medicine report. Furthermore, reprocessing is not discussed in either the 20 evidence-based Patient Safety Indicators established by the Agency for Healthcare Research and Quality or the 30 safe practices recommended by the National Quality Forum.

Although many studies have focused on human factors principles in health care settings (Barach, et al., 2008; Reason, 1995), there has been little study of the impact of human factors in reprocessing activities. Although the critical nature of sterilization and reprocessing has been addressed in some literature (Nelson, 2005; Rutala & Weber, 2001; Wendt & Kampf, 2008), the human factors in reprocessing errors have not yet been acknowledged, identified, or investigated.

A review of existing incident reports and safety alerts (Branaghan, Hildebrand, Epstein, Wu, Jolly, & Taggart, in preparation) suggests that most reprocessing incident reports place blame squarely on the human user. Thus, although the Institute of Medicine reports that as many as 98,000 people in the United States die annually from medical error, human factors researchers recognize that the remedy lies not in fixing humans, but in acknowledging the interaction between the human user and the product, environment, instructions, training, and/or operating procedures and designing better processes and products to accommodate this interaction. This approach emphasizes that the user is just one part of the system and realizes that insisting that the user makes fewer mistakes is less effective than designing a product, process, environment, and/or set of cognitive tools that make these mistakes less likely.

1.1. Reprocessing

Endoscope reprocessing includes precleaning, manual cleaning, and high-level disinfection or sterilization. Reprocessing errors may cause cross-infection during surgical or endoscopic procedures, potentially resulting in otherwise-preventable transmission of disease, resulting in enormous preventable mortality, morbidity, and medical costs. There are several challenges associated with endoscope reprocessing. One involves the wide variety of items that need to be reprocessed, each with its own set of standard operating procedures (SOPs) designed to mirror the manufacturer's instructions. For example, a particular hospital system may have several different models of GI endoscopes, in addition to bronchoscopes, laparoscopes, cystoscopes, arthroscopes, and others. A reprocessing technician will need to identify each type, make, and model, and apply the appropriate procedures in a busied environment. Another concern is the volume of scopes that are reprocessed where, depending on the health care 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).

Figure 1 shows a schematic of a flexible endoscope. Endoscopes can be difficult to disinfect and easy to damage because of their intricate design and delicate materials (Rutala & Weber, 2004). Furthermore, air and water channels are difficult to clean manually, and studies have indicated that bioburden often remains after cleaning (Ishino, Ido, Koiwai, & Sugano, 2001).

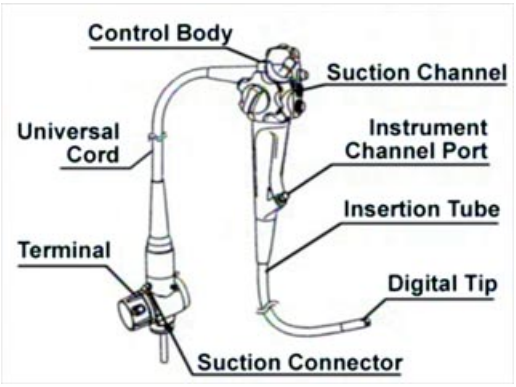

Figure 1 Schematic view of flexible endoscope, showing ports and channels.

Currently, there is no recognized method of verifying adequacy of endoscope reprocessing in routine practice and no data regarding current quality assurance practices. Users may be adhering to the reprocessing guidelines, but there is no structured feedback to confirm that they are completing the process correctly and adequately.

Endoscope reprocessing is a complex process composed of sequential subtasks, including precleaning, leak testing, cleaning, disinfecting, rinsing, drying, and storage (Rutala & Weber, 2004). The steps, briefly defined later in text, summarize what is often a 75-page manufacturer's instruction manual or a 30-page SOP. Cleaning removes soil from items and surfaces and typically is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.

1. Precleaning: Suction detergent through channels and flush with water. Remove valves and removable parts and soak in detergent solution. Transport to the reprocessing area.
2. Leak testing: Connect the scope to an air source and submerge it in clean water to check for escaping air bubbles, which indicate damage to the scope.
3. Clean: Mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with detergent or an enzymatic cleaner and water.
4. Disinfect: Disinfect endoscope through high-level disinfection or sterilization, depending on hospital capabilities. Sterilization destroys or eliminates microbes and is carried out using pressurized steam, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, and liquid chemicals. When this option is not available, immerse the endoscope in high-level disinfectant to 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 elimination 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. Two percent glutaraldehyde for 20 minutes will kill all microorganisms except large numbers of bacterial spores.
5. Rinse: Rinse the endoscope and all channels with sterile or filtered water.
6. Dry: Purge the insertion tube and inner channels with alcohol and dry with forced air. Dry the exterior of the scope with a lint-free towel.
7. Store: 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. Humans have limitations, and are prone to higher rates of errors and mistakes as the complexity of a task and level of stressors increase. Therefore, it has become necessary to take a human factors approach to examine current endoscope reprocessing procedures. The purpose of this study was to identify and create a baseline of human factors issues and to identify common usability problems and commonalities among them.

2. METHOD

2.1. Participants

Twenty-four nursing students (19 female and 5 male) between the ages of 18 and 54 were recruited through their university nursing programs, all located in the southwestern United States. Each participant had a basic understanding of infection control principles, but had no prior experience reprocessing endoscopes. Participants were paid for their participation.

2.2. Materials

This study was conducted in a nursing education classroom at a local nursing school. The following materials were visible to the participants at the beginning of the session:

- SOPs for endoscope reprocessing from a Veterans Health Administration (VHA) hospital
- Personal protective equipment
- Olympus GIF H160 endoscope
- Suction valve (MH-443)
- Air/Water valve (MH-438)
- Red contaminated transport container

- Lint-free cloths
- Prolystica Enzymatic Cleaner and 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)
- G180 portable suction machine
- 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
- Olympus instructional posters

2.3. Procedure

Participants were tested 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.

Next, participants watched a short video consisting of clips from a VHA orientation for new reprocessing technicians that introduced them to endoscopes and the reprocessing procedure. The video was seven minutes in duration. The experimenter then administered a short background questionnaire to gather information regarding participant demographics and knowledge of medical equipment and disease transmission.

Participants were provided with all the necessary directions and materials to complete their tasks and were given a scenario that resulted in them reprocessing an endoscope as if working independently. 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 then completed a short questionnaire and were encouraged to write additional comments on their experience of reprocessing an endoscope.

TABLE 1. Completion Rates and Times for the Four Reprocessing Tasks

Task	Mean (*SD*) Completion Time in Minutes	Mean Percent Error Free Completion (%)
Leak Testing	13.04 (3.65)	75.0
Manual Cleaning (Brushing)	34.29 (9.20)	40.9
Manual Cleaning (Flushing)	21.54 (4.62)	49.8
Drying	7.33 (2.06)	55.7
Total	76.21 (14.67)	

Then, the experimenter asked a set of debriefing questions and guided participants back through the procedure while prompting the participants to discuss subtasks that were particularly difficult to complete. Finally, the experimenter explained the relevance of the study, answered any questions, and paid the participant for his or her time.

3. RESULTS

For analysis we divided the reprocessing procedure into four tasks: 1) leak testing, 2) manual cleaning (brushing), 3) manual cleaning (flushing), and 4) simulated disinfection, drying, and storage. Completion rates and times for these tasks are shown in Table 1. Notably, none of the 24 participants completed the reprocessing procedure, or any of the four component tasks, without error. The table shows that the manual cleaning tasks, both brushing and flushing, were particularly problematic for participants. In each of those cases, fewer than half successfully completed the task. Performance on each task is discussed later in text.

Participants failed at many subtasks, so discussing each one in detail would make this section onerous. Instead, we have chosen to describe only the most critical problems here as 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) the potential risk for infection. If a subtask is included in more than one task, we discuss it only once.

TABLE 2. Successful Completion Rates for the Subtasks in Leak Testing

Subtask	Successful Completion (%)
Secure water-resistant cap	87.5
Insert leakage tester connector into leak testing unit	91.7
Turn on leak tester	100.0
Confirm leak tester is emitting air	62.5
Confirm leak tester's connector cap is dry	41.7
Confirm water-resistant cap's venting connector is dry	41.7
Attach leak tester connector to cap's venting connector	95.8
Verify pressurization	75.0
Immerse endoscope	95.8
Observe endoscope for leaks	16.7
Identify that no leak is present	75.0
Turn off leak tester	100.0
Disconnect leak tester connector from leak tester	58.3
Wait for endoscope to depressurize	75.0
Disconnect leakage tester connector from endoscope	91.7

3.1. Leak Testing

Table 2 shows the completion rates for leak testing. Leak testing employs a maintenance unit, which serves as an air compressor to pressurize the endoscope. To ensure that the maintenance unit is emitting air, participants must press on a small pin in the cap of a hose (leak tester connector) that runs from the maintenance unit to the endoscope. Many participants failed to identify the pin. Instead, because the maintenance unit was making noise, they assumed that the connector was emitting air.

Due to the small size of and dark openings in the leak tester and water resistant caps, participants had difficulty determining when components were dry. Furthermore, when disconnecting the leak tester connector from the maintenance unit, it is important to disconnect the connector from the maintenance unit *before* disconnecting from the endoscope. Doing this in the wrong order increases the likelihood of damaging the endoscope. Participants commonly disconnected them in the incorrect order.

When inspecting the scope for a leak, participants should use the endoscope's hand controls to bend the distal tip while looking for a continuous stream of bubbles in the water. Typically, participants failed to use the hand controls to bend the tip. Instead, they manipulated the tip by hand, increasing the risk of damaging the endoscope. Another problem stemmed from the wording of the SOPs, which instructed the user to angulate the bending section of the endoscope. Commonly participants believed the entire scope could be considered a bending section, and it was not clear that the instructions were referring to the distal tip.

3.2. Manual Cleaning (Brushing)

Table 3 shows the completion rates for the brushing portion of manual cleaning. We describe some of the main problems here.

The air/water and suction valves on flexible endoscopes are removable and reusable. A majority of participants failed to remove and immerse the endoscope's reusable parts. Because the SOPs did not identify the location of the parts on the scope, it was unclear what the reusable parts were and how they were to be removed (pulled, unscrewed, etc.). Furthermore, the SOPs identified the parts by their part numbers, which were printed on them in black text on a black background, yielding very poor contrast.

Before brushing, it is important to ensure that the distal tip of the endoscope moves freely and is straight, as failing to do so makes the scope susceptible to damage. This requires participants to use the hand controls to straighten and remove the locks on the distal tip and adjust the tension to its lowest setting. The user is not instructed how to get the scope to the free position. As a result, most participants failed to do this.

Only 1 of the 24 participants correctly located and brushed the instrument channel. On the endoscope, one entry leads to both the instrument and suction

TABLE 3. Successful Completion Rates for Subtasks in Manual Cleaning (Brushing)

Subtask	Successful Completion (%)
Confirm addition of enzymatic cleaner	62.5
Remove and immerse reusable parts	29.2
Set scope to free position	4.2
Wipe exterior of endoscope (keep immersed)	70.8
Straighten endoscope bending section	4.2
Insert brush into instrument channel	4.2
Push brush through channel	4.2
Clean brush with fingertips	23.2
Insert brush into suction channel	62.5
Push brush through channel	66.7
Remove brush correctly	50.0
Brush suction cylinder	66.7
Turn brush and remove	66.7
Brush instrument channel port	70.8
Turn brush and remove	58.3
Connect suction cleaning adapter to instrument channel port	62.5
Connect suction tube from suction machine to suction connector	41.7
Place finger or thumb over suction port	50.0
Turn suction machine on	91.7
Alternate suctioning	45.8
Turn suction machine off	70.8
Disconnect suction cleaning adapter and suction tube	79.2
Wipe exterior of reusable parts	37.5
Brush reusable parts	45.8
Brush channel openings	16.7
Flush openings of reusable parts with syringe	29.2
Depress pistons of each reusable part	33.3

channels, which are to be brushed by a long (approximately 60-inch) channel-cleaning brush. The participant must insert the brush into the same entrance as the suction channel, but at a 45° angle. Whereas the entrance to the suction channel is visible, the entry to the instrument channel, located at a 45° angle, is hidden. As a result, users often failed to locate the instrument channel and reasoned that some other hole on some other part of the endoscope was the right one. Even the manufacturer's posters were unclear about this arrangement, depicting both channels with the same color.

To avoid damage to the internal channels, users should use short strokes when removing the channel-cleaning brush. Many users, however, used long pulls to remove the brush.

Participants must use a suction machine to aspirate solution through the endoscope to help remove debris loosened by brushing. To do this, users connect two tubes to the endoscope: One tube pulls water into the scope, and the other pushes water out of the scope. Then the user must alternately cover and uncover the suction port on the endoscope with his or her finger. Sometimes participants connected the two tubes together, and other times they failed to cover and uncover the suction port, potentially bypassing or inadequately flushing one or more of the endoscope's channels.

Throughout the process many terms are similar. For example, in this subtask alone there is a suction machine, suction canister, suction port, suction connector, suction tube, suction cylinder, and suction cleaning adapter. The similarity among the various terms is likely to cause confusion.

3.3. Manual Cleaning (Flushing)

Table 4 shows the completion rates for the flushing portion of manual cleaning. We describe some of the main problems here.

TABLE 4. Successful Completion Rates for Subtasks in Manual Cleaning (Flushing)

Subtask	Successful Completion (%)
Immerse channel plug and injection tube	41.7
Attach the channel plug and injection tube	4.2
Flush solution through the air/water channel	66.7
Flush solution through the suction channel	66.7
Disconnect channel plug and injection tube from endoscope	45.8
Wipe exterior of endoscope	70.8
Transfer endoscope, parts, and equipment to container	75.0
Agitate endoscope and all parts	29.2
Depress pistons of each valve	37.5
Reattach the channel plug and injection tube	16.7
Flush water through the air/water channel	62.5
Flush water through the suction channel	70.8
Transfer endoscope, reusable parts, and equipment to towel	83.3
Inject air into reusable parts	16.7
Cover endoscope's distal end and control section with cloth	12.5
Flush air through the air/water channel	54.2
Flush air through the suction channel	58.3
Detach all reprocessing equipment	83.3

The first problem involves attaching the channel plug and injection tube. The injection tube attaches to four ports on the endoscope and is used to flush fluid through the internal channels while the channel plug blocks fluid from exiting the remaining ports. To facilitate proper setup, the manufacturer provides posters as well as instructions; however, it is difficult to ascertain which diagram, and even which poster, is the correct one to follow. Likewise, it is difficult to match the SOPs with the manufacturer's materials. Although the individual components of the injection tube are unlabeled, a label card is attached including part numbers for both the injection tube and the unattached channel plug. Users often believed the channel plug was part of the injection tube and failed to attempt to connect the channel plug. Even if participants did finally determine the correct arrangement, the channel plug required substantial dexterity to lock in place.

After participants flush fluid through the endoscope via the injection tube, they must remove the remaining fluid with an air flush. Frequently, users would fail to cover the distal tip of the endoscope, resulting in potentially contaminated water spraying at them, on other pieces of equipment, or on the floor, creating an unsafe work environment.

3.4. Simulated Disinfection, Drying, and Storage

Table 5 shows the completion rates for the simulated disinfection, drying, and storage. We refer to this task as simulated, because we did not in fact sterilize the endoscope, because running the sterilization machine requires one-half hour. Additionally, pilot testing suggested that this would extend the entire procedure to more than three hours for this set of naïve users.

The main problem with this task involved blowing water out of the endoscope's internal channels. The SOPs require the user to blow water out of all internal channels using compressed air. The tube from the air compressor seemed to fit one channel port particularly well. As a result, participants usually applied the compressed air only to that one channel, ignoring the others, and leaving water remaining in the endoscope. Drying only one channel is dangerous, because wet endoscope channels can foster bacterial growth.

3.5. Post-Test Questionnaire

Participants rated their agreement with the following statements using a scale ranging from 1 (strongly disagree) to 5 (strongly agree). The results, shown in

TABLE 5. Successful Completion Rates for Subtasks in Simulated Disinfection, Drying, and Storage

Subtask	Successful Completion (%)
Dry entire endoscope with a lint-free towel	95.8
Cover endoscope's distal end and control section with cloth	41.7
Blow out channels	25.0
Blow off entire exterior of endoscope	66.7
Remove water-resistant cap	70.8
Blow out and around water-resistant cap	62.5
Blow off reusable parts	37.5
Hang scope	45.8

TABLE 6. Responses to Post-Test Questionnaire Agreement Questions

Question	Mean (*SD*)
Reprocessing an endoscope was a physically challenging task.	2.67 (1.34)
I feel that the endoscope I reprocessed is clean enough to be used on a patient without further cleaning.	2.08 (1.02)
Reprocessing an endoscope involved a lot of things to remember.	4.33 (0.76)
Without the posters, the reprocessing task would have been more difficult.	4.54 (0.59)
If asked to reprocess another endoscope, I believe I could do it without referring to the written instructions.	1.54 (1.02)

Table 6, suggest that participants did not believe they could reprocess an endoscope on their own, and they did not believe that the endoscope they reprocessed was clean enough for use. Furthermore, they reported that the task required a great deal of memory to complete correctly.

In addition, participants rated the ease or difficulty of the following steps on a scale of 1 (very easy) to 5 (very difficult). Similar to the performance data, the responses in Table 7 show that participants found it difficult to 1) identify where the injection tube should be attached, 2) understand the specifics of conducting the leak test, and 3) locate which channels to brush. Furthermore, although manufacturer's instructions, posters, and SOPs were provided, participants felt that these materials were difficult to comprehend.

3.6. Preferred Training Method

Participants were asked to rank the effectiveness of the possible forms of training for reprocessing an

TABLE 7. Responses to Post-Test Questionnaire Difficulty Ratings

Question	Mean (*SD*)
Identifying where to attach leak tester connector on water-resistant cap	3.04 (1.16)
Understanding the instructions	3.71 (0.81)
Securing the water-resistant cap	2.25 (1.03)
Moving the endoscope from one container to another	1.88 (0.80)
Identifying if scope is pressurized	3.50 (1.18)
Knowing where to attach the connectors of the injection tube	4.13 (0.68)
Knowing how to aspirate solution through channels using the suction machine	3.54 (0.93)
Pushing fluid through channels using the syringe	2.33 (0.87)
Identifying which channels to brush	3.75 (1.03)

TABLE 8. Preferred Training Method

Training Method	Priority
Step-by-step audio instructions	4.25 (0.94)
Step-by-step written instructions	4.17 (0.87)
One-on-one training	1.17 (0.64)
Step-by-step instructional posters	3.21 (0.72)
Animated play-as-you-go video tutorial with step-by-step instructions	2.21 (0.78)

TABLE 9. Debriefing Comments

Comment	Number of Participants
Parts/tools hard to identify	20
Difficult to match written instructions with posters	10
One-on-one instruction would be better	10
Written instructions were confusing	9
Unsure if doing task correctly, or felt like they were making many mistakes	7
Trouble knowing where/how to use a tool	6
Training and practice is needed for this task	6
Written instructions and posters should be combined	6
Better labeling system needed	3
More visuals needed	3
Pictures helped	3
Scope was difficult to manage in sink	2
The task was difficult for someone short	2
Poster/pictures were confusing	2
More practice would make the task easier	2
Keeping place in the instructions was difficult	2

endoscope shown in Table 8 on a scale of 1 (most effective) to 5 (least effective). One-on-one training was ranked the most effective, with the animated video tutorial ranked as a close second.

3.7. Debriefing

Immediately after completing the reprocessing task, the experimenter prompted participants to discuss anything they were thinking or feeling regarding the task, as well as anything they felt was difficult or challenging. These comments were then organized into themes, and are shown in Table 9.

4. DISCUSSION

Because of its effectiveness in diagnosing and treating medical disorders and its minimally invasive nature, endoscopy is a common medical procedure. Furthermore, when an endoscope has been reprocessed according to the manufacturer's guidelines, it is safe. In contrast, there are more health care–associated outbreaks linked to contaminated endoscopes than to any other medical device (Rutala & Weber, 2004), and recent incidents of insufficient reprocessing have resulted in media attention and public concern. Endoscope reprocessing includes precleaning, manual cleaning, and high-level disinfection or sterilization to ensure that an endoscope is safe for reuse. The procedure requires hundreds of sequential steps, dozens of components, and inevitably, a significant amount of cognitive work from reprocessing technicians. If an endoscope has not been reprocessed according to these complicated guidelines, the potential to transmit Hepatitis B and Hepatitis C, as well as a host of other infectious agents, between patients increases significantly.

The human factors of reprocessing have received little scientific attention. Instead, problems often are blamed on the failure of medical personnel to comply with reprocessing standards. Rather than placing blame on the user, this usability test sought more useful explanations by focusing on the interaction between the user and the product, visuals, and instructions.

This is the first published usability test of endoscope reprocessing, and, indeed, any type of reprocessing for reusable medical equipment. Frequently, research in usability engineering has focused on the work of clinicians rather than support staff, such as reprocessing technicians. This is unfortunate, because the activities of the support staff affect every clinical procedure in the hospital. Exploratory in nature, this study identifies a baseline of human factors issues related to reprocessing endoscopes, and points out the most significant problems. It was designed to replicate the reprocessing procedure as viewed by a novice user who would require written instructions and visual aides to complete the task. A recording tool was used to reduce subjectivity and to obtain accurate quantitative data. This tool minimized the reprocessing procedure into 76 steps, and recorded the participant's ability to complete steps free of error, with error, or not at all. In addition, self-efficacy ratings from questionnaires and discussions with participants identified themes that are discussed in this section.

None of the participants successfully completed the entire procedure or, for that matter, any one of the four tasks within the procedure: 1) leak testing, 2) manual cleaning (brushing), 3) manual cleaning (flushing), and 4) simulated disinfection, drying, and storage. Twenty-three of 24 participants did not believe they had completed the reprocessing task satisfactorily.

4.1. Five Critical Subtasks

We identified 5 of the 76 subtasks as being particularly critical, based on 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) the potential risk of infection. For two of these five steps, only 4.2% of participants were able to complete the task free of error with the other three steps having completion rates between 17% and 46%.

The first critical subtask is to brush the instrument channel, which only 1 of the 24 participants correctly executed. Users should insert the brush into the same entrance as the suction channel, but at a 45° angle into a hole not visible from the exterior of the endoscope. As a result, participants often failed to brush the correct channel and reasoned that some other hole on some other part of the endoscope was the instrument channel.

This problem could be remedied by adding labels to all ports and channels on the endoscope. Diagrams could be modified to better illustrate the position of the instrument channel entrance and could be referenced by and integrated into the SOPs to reduce error due to the proximity between the visuals and the written instructions. On the next major redesign of the endoscope, the instrument channel could be relocated to make the entrance more visible.

The next critical subtask, also completed by only one participant, required the user to properly attach the channel plug and injection tube to the endoscope. To facilitate setup, the user is provided with diagrams and the SOPs, which have step-by-step instructions based on the manufacturer's guidelines. Participants found it difficult to match the correct diagram to the instructions, in part because individual components of the injection tube lacked labels and the instructions referenced only part numbers, not a specific diagram. To further complicate things, a label card on the injection tube includes part numbers for both the injection tube *and* the channel plug, a separate tool. Participants often believed the channel plug was part of the injection tube and left the channel plug unattached during this subtask. Even if participants knew to attach the channel plug, it required substantial dexterity to lock in place.

To improve this subtask, the individual components of the injection tube could be labeled and the misleading label card removed. Again, all ports and connectors on the endoscope itself could be labeled, and integration of the SOPs and visuals are recommended. The channel plug could be designed to lock in place by plugging it into the endoscope similar to the existing suction and air/water valves, removing the need for the current sliding lock mechanism. Also, the injection tube could be redesigned so that its separate components are combined into one or two plug connectors that attach to only one place on the endoscope.

A third critical step involves observing the endoscope for a leak, which requires pressurizing the submersed endoscope and using its hand controls to bend the distal

tip while looking for a continuous stream of bubbles in the water. Typically, participants manipulated the distal tip by hand, increasing the risk of damage. Wording of the SOPs also created confusion regarding which part of the endoscope should be bent and observed. Such issues illustrate the importance of clear instructions. Participants also had trouble discerning whether the endoscope was pressurized, a vital determination to subsequent leak-testing steps. Possible solutions include revising the SOPs to eliminate conflicting references to the same part (e.g., distal tip, distal end, bending section) and remove confusing nomenclature. The distal tip could be labeled with words or a picture to communicate using only the controls to bend the distal tip. A better diagram or analogy (e.g., testing a bicycle tire tube for a leak) could be provided to communicate what a leak looks like. A pressure indicator could be implemented into the design of the endoscope itself instead of relying on a separate step to conclude that the endoscope is pressurized.

A fourth subtask of interest involved blowing water out of the endoscope's internal channels at the end of the simulated disinfection, drying, and storage task. Instructions require the user to blow water out of all internal channels using compressed air, but do not give details about how to do this. As a result, participants usually left water remaining in the endoscope, which can foster bacterial growth. To address this problem, a diagram with details and cues to look for when this step is complete (e.g., no water comes out for three seconds) could be developed.

In the final critical subtask, one uses a suction machine to aspirate solution through the endoscope to remove debris loosened by brushing. To do this, users connect two tubes to the endoscope and alternate covering and uncovering the suction port on the endoscope with their finger. Sometimes participants connected the two tubes together and other times they failed to cover and uncover the suction port, potentially bypassing or inadequately flushing one or more of the endoscope's channels. Again, this could be improved by integrating diagrams into the SOPs as well as labeling all parts of the endoscope and tools used during reprocessing. Because it appeared that suctioning occurred in a variety of ways that deviated from the SOPs, a follow-up study could be conducted to determine if alternating covering and uncovering the suction port provides a significant reduction of bioburden. The study could ultimately assess the necessity of this step in its current form.

4.2. Three Themes

Three themes run through the majority of problems identified in the usability test: lack of visibility, high memory demands, and inconsistent feedback.

4.2.1. Lack of Visibility

Parts and tools that are difficult to see or understand make tasks difficult to complete. In this test, errors related to lack of visibility were due to poor contrast or positioning of a label, the lack of a label, a poor match between diagrams and the product, and important elements of the endoscope that are not visible from the exterior. Ways to increase visibility include introducing new (or modifying existing) labels on all parts and tools. In doing so, attention should be paid to the location, contrast, and meaningfulness of the labels. Furthermore, SOPs and manufacturer's instructions should be improved to show diagrams of the endoscope in the same orientation as the user views it. Finally, all parts with which the user interacts should be clearly visible from the exterior.

4.2.2. High Memory Demands

Reprocessing involves dozens of parts, conflicting diagrams, and hundreds of sequential steps. The sheer volume of materials and steps alone are enough to tax a user's memory, especially if users are likely to get interrupted. Additionally, part names and identifying numbers are often long and too similar to one another. To reduce memory demands, reduce the number of parts and tools that have similar or complicated names. Integrate diagrams into the SOPs to reduce errors related to incorrect matching. Eliminate complex nomenclature and conflicting directions and labels in the SOPs. Add sufficient emphasis to crucial steps and introduce a visual checklist to remind users of the status of steps and limit any from being accidentally omitted.

4.2.3. 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. To improve feedback, introduce into the instructions some of the strong, existing forms of feedback to look for at the completion of a step. Create new forms of

feedback where none is available and eliminate conflicting feedback with the redesign of equipment.

Of course, there were limitations to the usability test. For one, it did not investigate what effects the work environment may have on performance, nor did it examine the selection of personnel for this task. It also assumes that the reprocessing technician is completing the entire procedure manually apart from the high-level disinfection process where an automated endoscope reprocessor (AER) will take over. We are aware of AER machines that purportedly complete several steps that were investigated in this study, but to date no machine has been shown by independent studies to eliminate sufficient bioburden to exclude the brushing steps of manual cleaning. In addition, any AER machine will need to be hooked up to the endoscope to complete reprocessing, a task similar to attaching the injection tube, which was one of the problematic steps found in this study with only a 4.6% completion rate.

Novice users (nursing students), rather than expert reprocessing technicians, were chosen as our participants. This decision was based on the need for simulating hospital employees who had completed an orientation involving basic knowledge of disease transmission and to detect as many usability problems as possible. Although these participants are less practiced than expert technicians, they tended to be better educated than many reprocessing technicians.

Due to recent public concern regarding the safety of endoscopy procedures and the greater difficulty in reprocessing this instrument, we chose to focus on GI endoscopes for this study. The type of endoscope we chose was identical to the most popular model currently used in the United States for GI endoscopies, with the main differences being the lack of a high-definition camera (irrelevant for reprocessing) and an auxiliary water port. The set of SOPs chosen for this study correlated well with the manual reprocessing procedure provided by the manufacturer's instructions. Additionally, they were quite similar to the majority of other SOPs for endoscope reprocessing we have worked with across the United States.

Future research should investigate the value of improving labeling to increase visibility of reprocessing components. Such a study could vary the location, contrast, size, and type of labels used. This improvement seems important because 20 of 24 participants in our study commented that parts and tools were difficult to identify. Furthermore, the ability to identify parts and tools was relevant in all five of the most problematic steps discovered in this study.

Another study should focus on integrating diagrams directly into the SOPs or reprocessing instructions. Ten of 24 participants mentioned that they had difficultly matching visuals with written instructions. Also, nine found the written instructions confusing, and 83.3% believe that a diagram with animations would be more effective than written or still visuals alone.

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