Exploring Human Factors in Endoscope Reprocessing

Article *in* Human Factors and Ergonomics Society Annual Meeting Proceedings · September 2010

DOI: 10.1177/154193121005401219

CITATIONS
5

READS
445

10 authors, including:

Russell J Branaghan
Arizona State University
51 PUBLICATIONS **234** CITATIONS
SEE PROFILE

Judith L Babcock-Parziale
Southern AZ VA Health Care System
30 PUBLICATIONS **271** CITATIONS
SEE PROFILE

Exploring Human Factors in Endoscope Reprocessing

Emily A. Hildebrand[1], Russell J. Branaghan[2], Qiawen Wu[2], Jonathan Jolly[2], Theodore B. Garland[2], Mistey Taggart[2], Monica A. Nguyen[2], Dana R. Epstein[1], Judith Babcock-Parziale[3], Victoria Brown[3]

[1]Phoenix VA Health Care System, [2]Department of Applied Psychology, Arizona State University, [3]Southern Arizona VA Health Care System

Abstract: The goal of this research is to study the human factors that influence the reprocessing of flexible endoscopes. This paper will report on the preliminary findings from a heuristic evaluation of current reprocessing procedures from an ongoing multi-method study and will discuss the implications of the results for future research purposes.

Introduction

In the United States, more than 46 million surgical procedures are conducted annually, and there are even more non-surgical invasive procedures (Rutala, Weber, & Healthcare Infection Control Practices Advisory Committee, 2008). Approximately 10 million of the non-surgical procedures are gastrointestinal endoscopies using flexible endoscopes, which are valuable tools used to diagnose and treat medical disorders (Rutala & Weber, 2004). The number of endoscopes in use is impressive. For example, the United States Veteran's Health Administration (VHA) owns 9,200 endoscopes worth $185,000,000. Annually, there are 5,200 repair episodes totaling 12.5 million dollars.

Endoscopes must be reprocessed after each procedure. Reprocessing is a multi-step procedure that renders a contaminated endoscope safe for reuse (Muscarella, 2000). Failing to properly reprocess a medical device carries the risk of person-to-person transmission of viruses such as hepatitis C, HIV, or other bacteria, as well as the transmission of environmental pathogens such as pseudomonas (Nelson, 2003).

While the incidence is low, there are more healthcare-associated outbreaks linked to contaminated endoscopes than to any other medical device (Rutala & Weber, 2004). Because of the body cavities they enter, flexible endoscopes receive high levels of contamination during each use (Rutala, Weber, & Healthcare Infection Control Practices Advisory Committee, 2008). Further, they have intricate and expensive designs with long narrow channels, removable and disposable parts, so they tend to be difficult to clean and rather easy to damage (see Figure 1).

As a result, proper disinfection and sterilization is critical. Indeed, the most common reasons for disease transmission with endoscopes are unacceptable cleaning, using an improper disinfecting agent, failing to follow recommended cleaning and disinfection procedures (Nelson, 2003; Spach, Silverstein, & Stamm, 1993), and flaws in endoscope design (Kirschke et al., 2003) or automated endoscope reprocessor design (Weber & Rutala, 2001).

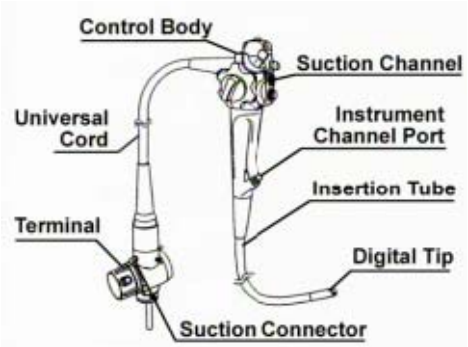

Figure 1. Flexible Endoscope

Failure to follow guidelines continues to yield infections associated with endoscopes (Weber & Rutala, 2001; Mehta et al., 2006). One study found that almost 24% of the bacterial cultures from the internal channels of 71 gastrointestinal endoscopes grew substantial colonies of bacteria after completion of all disinfection and sterilization (Rutala et al., 2008). Though it is widely agreed that published recommendations for cleaning and disinfecting should be strictly followed, audits have shown that personnel do not adhere to guidelines on reprocessing (Honeybourne & Neumann, 1997; Jackson & Ball, 1997) and outbreaks of infection do occur (Agerton et al., 1997; Bronowicki, Venard, Botte, Monhoven, Gastin, & Chone, 1997; Michele et al., 1997).

There are several obvious challenges associated with the activities surrounding reprocessing. One involves the wide variety of items that need to be reprocessed, each with their own method, instructions and standard operating procedures (SOP's). For example, a particular hospital system may have several different models of gastrointestinal 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 busy environment. Another concern is the volume of scopes that are reprocessed. Depending on the healthcare facility, an individual reprocessing technician often reprocesses as many as forty endoscopes per day, each requiring up to 40 minutes.

Surprisingly, the link between reprocessing errors, infection, and human factors has received relatively little public or scientific attention. A review of existing incident reports and safety alerts (Branaghan, Hildebrand, Epstein, Wu, Jolly, & Taggart, in preparation) suggests that most endoscope reprocessing incidents occur as a result of human error in abiding by mandated guidelines. These reports place blame squarely on the human operator rather than taking into account the interaction between the operator and the product, as well as the manufacturer's instructions, training curriculum, and operating procedures. Design flaws are often disguised as human error. Thus, while the Institute of Medicine (Kohn, Corrigan, & Donaldson, 1997) reports that as many as 98,000 people in the U.S. die annually from medical error, human factors researchers recognize that the remedy lies not in fixing humans but in designing better processes and products.

This paper presents a first step on the way to understanding the human factors of endoscope reprocessing. It reports the results of a heuristic evaluation of the reprocessing of the Olympus GIF 180, the most commonly used gastro-intestinal endoscope in the United States. First it reviews the human factors issues found in this evaluation. Then it discusses the implications of these findings for product and process redesign.

The Reprocessing Procedure

Endoscope reprocessing is a complex procedural task composed of sequential subtasks. It is recommended that users follow manufacturer's guidelines and facility SOP's above all else. Although specifics may vary, the process always involves the steps listed below. These steps summarize what is typically a 75-page manufacturer's instruction manual or a 30-page SOP.

1. Pre-clean: Suction detergent channel and flush water through air/water channel. Remove valves and removable parts and soak in detergent solution. Transport to reprocessing area
2. Leak test: Connect the scope to an air source and submerge it in clean water to check for escaping bubbles, which indicate damage.
3. Clean: Mechanically clean internal and external surfaces. Brush internal channels and flush each channel with water and detergent or enzymatic cleaners.
4. Disinfect: Immerse the endoscope in high level disinfectant and perfuse disinfectant into all accessible channels and expose for a recommended amount of time.
5. Rinse: Rinse the endoscope and all channels with sterile or filtered water.
6. Dry: Rinse the insertion tube and inner channels with alcohol and dry with forced air after disinfection and before storage.
7. Store: Hang the endoscope vertically in a closed, well-ventilated container to promote drying and prevent recontamination.

Heuristic Evaluation

A heuristic evaluation is a useful, efficient, low-cost, and easy-to-apply method for identifying usability problems in a product or process (Nielsen, 1993). This enables researchers to become familiar with the reprocessing procedure while identifying potential human factors issues that may result in error. This key step provides an initial look at the issues and the results that have directed our research focus.

Method

For these evaluations, we reviewed the endoscope reprocessing procedure as it was described in an informational video used to train endoscope reprocessing technicians. When clarification was needed, evaluators referenced the instructional manual for the Olympus GIF 180 Series model. We utilized a heuristic evaluation method modified specifically for evaluating medical devices (Zhang et al, 2003) (see Table 1).

Table 1. Nielsen-Shneiderman Heuristics

Heuristic	Definition
Consistency	Users should not have to wonder whether different words of situations or actions mean the same thing.
Visibility	Inform users about what is going on with the system through appropriate display of information.
Match	The image of the system perceived by users should match the model the users have.
Minimalist	Any extraneous information is a distraction and a slowdown.
Memory	Don't require users to memorize a lot of information. Memory load reduces user's capacity to carry out the tasks.
Feedback	Give users prompt and informative feedback about their actions.
Flexibility	Users always learn and are always different. Give users flexibility of customization and shortcuts to up performance.
Message	Messages should be informative enough so that users understand the nature of errors, learn from errors, and recover from errors.
Error	It's better to design interfaces that prevent errors from happening in the first place.
Closure	Every task has a beginning and an end. Clearly notify users about the completion of a task.
Undo	Allow users to recover from errors. Reversible actions also encourage exploratory learning.
Language	Language should be always presented in a form understandable by the intended users.
Control	Don't give users the impression that they are controlled by the systems.
Document	Always provide help when needed.

Included in the heuristic evaluation method defined by Zhang was a severity scale that we modified to better rate the usability problems within this process. When a heuristic is

violated, the issue is given a severity rating based on the likelihood that contamination will occur as a consequence. The scale is as follows,

1 = Negligible, or not likely

2 = Low likelihood

3 = Medium likelihood

4 = High likelihood

Using a standardized worksheet (see Figure 2), a team of five independent raters (three graduate, and two undergraduate human factors students) evaluated the endoscope reprocessing procedure and device design to identify violations of the heuristics. Each evaluator observed the training video and recorded the time, reprocessing stage, and a description of the violation.

HEURISTIC EVALUATION WORKSHEET					
EVALUATOR: Mr. Example					
DATE: xx/xx/xx					
SYSTEM: Reprocessing Training Video					
TIME	HEURISTIC	PHASE	DESCRIPTION	SEVERITY	POSSIBLE FIX
1:30	Error	Cleaning	User could choose the wrong brush size to clean the channels with.	3	Use color coded brushes that match the channel they should be used for.

Figure 2. Evaluator worksheet

Each evaluator then reviewed the violated heuristics, assigned severity ratings to the violation, and suggested a possible solution to the problem. The five separate evaluations were then compiled into a master list that highlighted several areas of potential trouble for reprocessing technicians.

Results

Figure 3 shows the frequency of heuristic violations for the reprocessing procedure. Evaluators identified 324 unique usability problems. Since each problem could violate more than one heuristic, there were 662 heuristic violations. Memory, feedback and visibility were the most common.

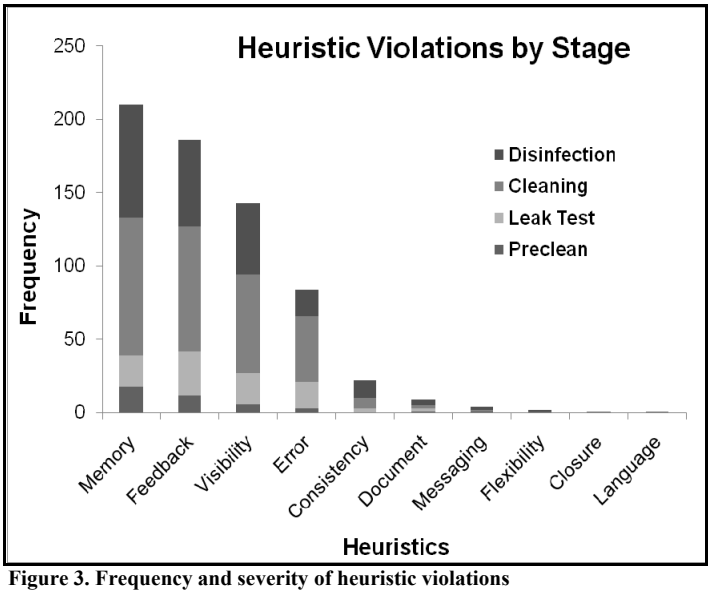

Figure 3. Frequency and severity of heuristic violations

Indeed, those three heuristics accounted for 81% of the violations. Note that the error heuristic does not imply the occurrence of an actual error, but instead indicates a situation where the product or process could be better designed to prevent an error. The violations included a wide array of issues; however certain violations were found unanimously among all evaluators. Examples of those occurrences will now be discussed**.**

A common violation of the feedback heuristic was a step in Leak Testing. To check for leaks, technicians must connect the scope to a pressurized air source and look for expansion in the bending section of the distal tip (see Figure 4). The tip of the scope is small and hard to see, making it difficult for the technician to determine if the scope is properly pressurized. Further, most directions fail to describe how much expansion is appropriate, leaving it entirely up to the technician to determine the necessary amount of air pressure. If a scope is not properly pressurized, the technician may fail to detect leaks and scope damage during this step.

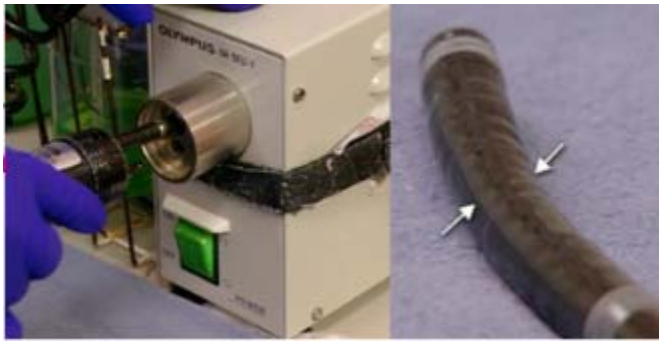

Figure 4. Scope connecting to air source and expanded distal tip.

Violation of feedback also occurs during the Cleaning stage of the process when technicians are required to use a suction machine to flush the internal channels with detergent solution. For this step, the user must attach two suction tubes to the endoscope, turn on the suction machine, and alternate covering and uncovering one of the channel openings. Improper attachment of one or both of the suction tubes may still allow the user to pull fluid through the endoscope appearing to complete the task. However, this task would be incorrectly and most likely leave some internal channels unaffected without the technician knowing.

The total number of steps in the reprocessing procedure is enough to violate many memory heuristics, however additional issues were found with the scope design and cleaning procedure which reinforce this problem. For example, a step in the Cleaning Stage requires technicians to brush two channels that reside in the same opening. One channel is cleaned by inserting a brush directly (at a 180° angle) into the opening and the other channel is cleaned by inserting the brush into the same channel opening at a 45° angle. Technicians have to remember which opening has two channels and then have to recall how to insert the brush to thoroughly clean each channel, all without being able to visually see where the brushes are going (see Figure 5).

Figure 5. Two channel openings on scope control body

Another violation of memory involves the attachment of the injection tube and channel plug, which are necessary to manually flush the internal channels of the endoscope during the Cleaning Stage. The injection tube has five different "legs" or ends that appear to attach to something else, while the channel plug has two. The user must remember to attach all five legs to the appropriate places on the endoscope before manual flushing to ensure all internal channels are effectively cleaned.

A common visibility violation occurred during the Cleaning Stage, where technicians must brush multiple internal channels with small brushes (see Figure 6). Some of the brushes are different sizes to accommodate the different channels and serve different functions. Also, different scope models require different brushes. It would be easy for a technician to choose the wrong brush since most appear to be very similar visually (same shape, same color). If a technician uses a brush that is too small for a channel they will fail to remove all the debris, and the scope could remain contaminated. If the technician uses a brush that is too large for a channel they may cause damage to the interior of the scope.

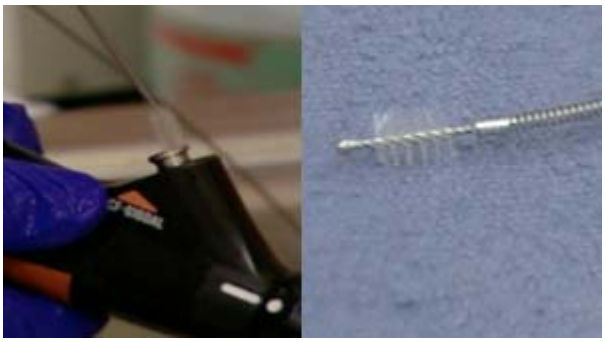

Figure 6. Example of cleaning brush used to remove debris from scope channels

Discussion

The findings from this heuristic evaluation confirm that flexible endoscope reprocessing procedure can be error prone. Memory, feedback, and visibility were the most commonly violated heuristics and tended to receive the most severe ratings. Most importantly, this evaluation reveals that this procedure is an incredibly difficult process that places a large cognitive and perceptual load on the user.

Aside from the potential problems revealed in the heuristic evaluation, a wide variety of issues were identified that may be contributing factors to problems in the reprocessing procedure. We have organized these topics into several major categories that ultimately need to be further examined and improved upon.

Design problems. The endoscope itself is an awkward tool that is expensive and complex. It is uniquely shaped, intricately designed, and contains delicate components that need to be handled with care. These factors are not conducive to a product that has a high usage rate and is subjected to strong manual cleaning and high level disinfection processes multiple times a day. Indeed, the scope design is not favorable to memory. There are numerous removable, disposable and attachable parts which technicians must either commit to memory or continually refer to pictures in a manual to identify them. Human factors principles could remedy these problems. The use of color coding or labeling of specific parts of the endoscope could serve as indicators or affordances that are easy, cost-efficient solutions and can be quickly implemented.

Procedural Problems. A consequence of the design of the scope is the procedure by which it needs to be reprocessed. This process requires numerous sequential steps, multiple scope attachments and cleaning accessories, and much cognitive ability from the technician. While instructional manuals and standard operating procedures are available, it's not beneficial or realistic for a technician to constantly refer to these extensive guides when under the time pressures of the reprocessing workroom. The procedure is not intuitive and the evaluators in this study found that the steps were not organized in a manner that promoted memorization. Ultimately, a more intuitively designed scope may yield a more intuitive reprocessing procedure. Until then, a simple and efficient redesign of the procedures may promote more compliance with the guidelines among technicians.

Lack of feedback. A reprocessing technician has numerous steps, materials, and considerations to remember. However, the reprocessing procedure lacks consistent and clear methods of informing the technician where they are at in the process at any given time. Evaluators noted that errors were likely to occur because there was a lack of feedback to notify the technician if they completed a step, completed a step adequately or failed to complete a step at all. Often, technicians work in small rooms where they reprocess multiple scopes simultaneously and must switch between cleaning scopes at different points in the process. More feedback, indicators and affordances that inform the technician of when steps are completed and where they are at within the procedure could potentially reduce errors from occurring.

Personnel Problems. It has been documented that compliance with approved reprocessing guidelines is a problem (Moses & Lee, 2004), thus it is possible that the current means of personnel selection and training may be a factor in reprocessing errors. Perhaps the types of people selected for these positions are not qualified to perform tasks of such importance or do not have the right kind of training to efficiently complete this task. Future research may need to focus on the types of people being chosen for these positions,

how they are selected, how they are trained, and how they are measured for competency.

Environmental Problems. The environment of a reprocessing technician consists of high workloads and high pressure. Reprocessing workrooms are typically small, cluttered and disorganized. Research that applies human factors principles to redesigning the environment could benefit the reprocessing procedure by creating a safer, more efficient, and more compatible workspace.

Conclusion

It is known that humans are prone to error. However errors in the healthcare environment can have dire consequences, including transmission of disease, and death. Flexible endoscopes have shown the ability to compromise the health of individuals when they are reprocessed incorrectly. This heuristic evaluation has confirmed that the current reprocessing procedures and device design are problematic, especially in relation to the cognitive and perceptual capacities of the users. Future research is needed to investigate these issues in the reprocessing procedure as well as other areas of influence including product design, training, personnel, and the workroom environment.

References

Agerton, T., Valway, S., Gore, B., Pozsik, C., Plikaytis, B., Woodley, C., et al. (1997). Transmission of a highly drug-resistant strain (strain W1) of mycobacterium tuberculosis: Community outbreak and nosocomial transmission via a contaminated bronchoscope. *JAMA: The Journal of the American Medical Association, 278*(13), 1073-1077.

Branaghan, R.J., Hildebrand, E., Epstein, D.R., Wu, Q., Jolly, J., & Taggart, M. (in preparation). Toward an Understanding of Human Factors in Reprocessing Safety.

Bronowicki, J., Venard, V., Botte, C., Monhoven, N., Gastin, I., Chone, L., et al. (1997). Patient-to-patient transmission of hepatitis C virus during colonoscopy. *The New England Journal of Medicine, 337*(4), 237-240.

Honeybourne, D., & Neumann, C. S. (1997). An audit of bronchoscopy practice in the united kingdom: A survey of adherence to national guidelines. *Thorax, 52*(8), 709-713.

Jackson, F. W., & Ball, M. D. (1997). Correction of deficiencies in flexible fiberoptic sigmoidoscope cleaning and disinfection technique in family practice and internal medicine offices. *Archives of Family Medicine, 6*(6), 578-582.

Kaczmarek, R. G., Moore, R. M., Mccrohan, J., Goldmann, D. A., Reynolds, C., Caquelin, C., et al. (1992). Multi-state investigation of the actual disinfection/sterilization of endoscopes in health care facilities. *The American Journal of Medicine, 92*(3), 257-261.

Kirschke, D. L., Jones, T. F., Craig, P. S., Chu, P. S., Mayernick, G. G., Patel, J. A., et al. (2003). Pseudomonas aeruginosa and serratia marcescens contamination associated with a manufacturing defect in bronchoscopes. *New England Journal of Medicine, 348*, 214-220.

Michele, T. M., Cronin, W. A., Graham, N. M. H., Dwyer, D. M., Pope, D. S., Harrington, S., et al. (1997). Transmission of mycobacterium tuberculosis by a fiberoptic bronchoscope: Identification by DNA fingerprinting. *JAMA: The Journal of the American Medical Association, 278*(13), 1093-1095.

Kohn, L.T., Corrigan, J.M., & Donaldson, M.S., (1997). *To Err is Human: Building a Safer Healthcare System*. National Academies Press.

Mehta, A.C., Prakash, U.B.S., Garland, R., Haponik, E., Moses, L., Schaffner, W., et al. (2006). Prevention of flexible bronchoscopy-associated infection. *Chest, 128*, 1742.

Muscarella, L. F. (2000a). Automatic flexible endoscope reprocessors. *Gastrointestinal Endoscopy Clinics of North America, 10*(2), 245-257.

Nelson, D. B. (2003). Infectious disease complications of GI endoscopy: Part II, exogenous infections. *Gastrointestinal Endoscopy, 57*, 695-711.

Nielsen, J. (1993). *Usability Engineering*.Cambridge, MA: Academic Press Professional.

Rutala, W. A., Weber, D. J., & Healthcare Infection Control Practices Advisory Committee. (2008). *Guideline for disinfection and sterilization in healthcare facilities, 2008*. Atlanta, GA: Centers for Disease Control and Prevention.

Rutala, W. A., & Weber, D. J. (2004a). Disinfection and sterilization in health care facilities: What clinicians need to know. *Clinical Infectious Diseases, 39*(5), 702-709.

Rutala, W.A. & Weber, D.J. (2004b). Reprocessing endoscopes: United States perspective. Journal of Hospital Infection, 56, S27-S39.

Spach, D. H., Silverstein, F. E., & Stamm, W. E. (1993). Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Annals of Internal Medicine, 118*(2), 117.

Weber, D. J., & Rutala, W. A. (2001). Lessons from outbreaks associated with bronchoscopy. *Infection Control and Hospital Epidemiology, 22*(7), 403-408.

Zhang, J., Johnson, T.R., Patel, V.L., Paige, D.L., Kubose, T. (2003). Using usability heuristics to evaluate patient safety of medical devices. Journal of Biomedical Informatics. 36, 23-30.