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An Expert Perspective of Errors in Endoscope Reprocessing

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Abstract: Endoscope reprocessing has been identified as a complex procedure that, when completed incorrectly, can lead to patient outbreaks due to cross contamination. Most reported incidents cite human error as the cause, but little research to date has explored the human factors related issues surrounding reprocessing procedures. The purpose of this study was to interview experts in endoscope reprocessing to determine the most difficult steps and error prone tasks in the procedure as well as identify potential contributing factors to error. Relationships between tasks and contributing factors are examined and implications for future research are discussed.

Introduction

In the United States alone, it has been estimated that 15 million procedures involving flexible endoscopes are performed annually (Humphrey & Kovach, 2006) and contaminated endoscopes have been associated with more health-care outbreaks than any other medical device (Rutala & Weber, 2004). While the incidence of infection is statistically low, flexible endoscopes have recently garnered a lot of attention for continued failures in reprocessing practices across the U.S. (Seoane-Vazquez & Rodriquez-Monquio, 2008).

Flexible endoscope reprocessing is a complex procedure that renders a contaminated endoscope safe for reuse (Muscarella, 2006). Endoscopes have intricate and delicate designs with long narrow channels, hinges and crevices, so they tend to be difficult to clean and rather easy to damage (Figure 1) (Rutala & Weber, 2004). Failure to properly reprocess a medical device can result in the transmission of infectious viruses including Hepatitis B, Hepatitis C, HIV, and other bloodborne pathogens (Weber & Rutala, 2001; Nelson, 2003; Pennsylvania, 2010).

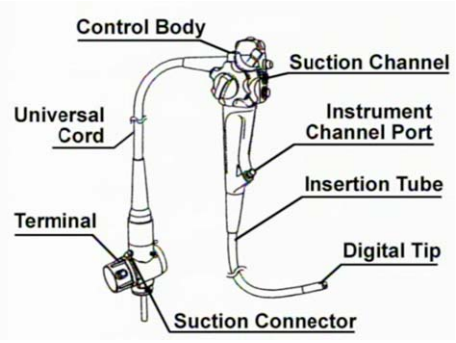

Figure 1. General flexible endoscope

Most literature and incident reports to date blame the reprocessing technicians, identifying a failure to follow established cleaning protocols as the cause for cross contamination (Pennsylvania, 2010). However, multiple studies have found that endoscopes often remain contaminated despite close adherence to reprocessing procedures (Seoane-Vazquez, Rodriquez-Monguio, & Carlson, 2007). 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). So, while the Institute of Medicine 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 products and processes.

There are several obvious challenges associated with endoscopes and reprocessing procedures. First, there is a wide variety of devices continually in need of being reprocessed. 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 reprocessing procedure, typically in a busied environment. Further, depending on the healthcare facility, an individual technician could reprocess as many as 30 endoscopes per day, each requiring up to 40 minutes to complete (multiple endoscopes may be in various stages of reprocessing at once).

Recent research has taken preliminary steps towards addressing and validating some of the challenges in endoscope reprocessing. Hildebrand et al (2010) conducted a heuristic evaluation of the endoscope design and reprocessing procedure. Multiple product design problems were found to violate users' capacities for memory, vision, and feedback. Jolly et al (2011) further validated these initial findings in a usability study examining the challenges novice users face in completing the reprocessing procedure. Again, it was found that the main contributing factors to error include high memory demands, lack of visibility and poor feedback. These findings highlight that this complex procedure combined with poorly designed products are overloading the cognitive and perceptual capabilities of the users.

The approaches thus far have targeted identifying potential design problems and novice usability errors in a lab

setting. The next step is to examine how those results compare to problems experienced by current users conducting endoscope reprocessing. One method of acquiring this information is to interview the experts in endoscope reprocessing. Expert users possess richer mental models, enhanced perceptual skills, and tend to operate at a higher level of procedural understanding (Crandall, Klein, & Hoffman, 2006). Typically, in endoscope reprocessing, expert technicians are responsible for training new personnel. Their acquired strategies and rules of thumb are often passed on to assist others in learning how to overcome challenging tasks in the procedure. Examining this knowledge experts acquire through experience may reveal what is difficult for other users to learn or grasp, and also highlight areas that could benefit from human factors design solutions.

It's apparent that the reprocessing procedure is time consuming, physically engaging, and cognitively demanding (Jolly et al, 2011). Humans have limitations, and are prone to higher rates of errors as the complexity of a task and level of stressors increase. Therefore, it is essential to take a human factors approach to examine current endoscope reprocessing personnel and procedures in order to determine effective solutions.

The purpose of this study was to utilize expert knowledge within the reprocessing field to identify human factors problems in the endoscope reprocessing procedure. Interviews with expert reprocessing technicians allowed us to characterize errors that are likely to occur, discuss commonalities among them and potentially identify contributing factors.

The Reprocessing Procedure

Endoscope reprocessing is a complex process composed of sequential subtasks including pre-cleaning, leak testing, manual cleaning, disinfecting, rinsing, drying, and storage (Rutala & Weber, 2004). An informal task analysis, completed by the authors, revealed there are over 200 individual steps that comprise the overall reprocessing procedure. Currently, there is no recognized method of verifying adequacy of endoscope reprocessing in routine practice. That is, 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. The major stages, briefly defined below, summarize what is often a 75-page manufacturer's instruction manual or a 30-page set of standard operating procedures (SOP).

1. Pre-cleaning: 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.
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. Disinfection or sterilization: Most facilities utilize automated endoscope reprocessors (AERs) to complete high level disinfection.
5. Rinse: Flush all internal channels with sterile or filtered water.
6. Dry: Purge the internal channels with alcohol and dry with forced air.
7. Store: Hang the endoscope vertically in a well ventilated cabinet or storage container.

Methods

Using basic principles borrowed from cognitive task analysis techniques, a semi-structured interview was created to capture expert knowledge about common problems in flexible endoscope reprocessing.

Study sites and subject recruitment

Various Level 1 hospitals were chosen as interview sites. Gastrointestinal (GI) endoscope reprocessing technicians were asked to participate in the study. For technicians to qualify for the study, it was required that they regularly reprocess 10 or more GI endoscopes per week. All participants were ensured that this interview was not a test and that the researchers were interested in learning from the knowledge and experience they possess for the endoscope reprocessing procedure.

Eleven technicians were interviewed in total with experience ranging from 2 – 15+ years. All participants worked full time as endoscope reprocessing technicians whose sole job tasks included the reprocessing of flexible endoscopes (i.e. they did not partake in patient care procedures). The average number of endoscopes reprocessed per week varied by site (from 25 per week to 150 per week) with an overall average of 18 scopes per day.

Interview

The research team met with each participant at a scheduled time in a secluded room. Personally identifiable information was not collected.

Prior to the interview, the researcher stated that there would be a questionnaire to complete. The questionnaire listed all of the fundamental tasks in the endoscope reprocessing procedure, as defined by Olympus (2005). For time purposes, this questionnaire contained 98 basic tasks that comprise the leak testing, manual cleaning, high level disinfection (using an AER), rinsing/drying, and storage portions of the reprocessing procedure. Subjects were asked to consider each basic step in the reprocessing procedure and think about troubles or difficulties that new reprocessing technicians may encounter. Subjects were advised to draw on experience from: 1) training new technicians, 2) when they were new technicians themselves, or 3) current everyday frustrations. With that information in mind, the subjects then rated each step on the likelihood that a new reprocessing technician may commit an error. Ratings were made on a 1-5 likert scale, 1 = low likelihood and 5 = high likelihood.

Following the questionnaire, subjects were interviewed, specifically on tasks they rated with a 3 (medium likelihood an error will occur) or higher. The researcher started by verbally clarifying the rating that the participant gave for a particular task. Next, the participant was asked to consider and discuss that specific task in depth, focusing on the following questions: What is easy and what is difficult about it? What information is needed to conduct the subtask? What can go wrong? What are the common errors likely to occur? What can be improved? What feedback is provided regarding whether the subtask was completed correctly or incorrectly? What is done to speed this process up (i.e. shortcuts)?

To conclude the experiment, the participant was asked to fill out a short survey to gather some informational data including years of experience and the average number of scopes reprocessed per week.

Results

This study produced quantitative (ratings provided by participants) and qualitative (information from interviews) data. The ratings from all participants were combined and average scores were calculated for each step. Table 1 shows the top fifteen highest rated steps.

*Table 1. Top 15 Error Prone Steps**

Step	Mean(SD)
Observe for 30 seconds while angulating the bending section (leak testing)	2.55(2.50)
Wait 30 seconds, or until bending section contracts to its pre-expansion size	2.82(3.00)
Straighten endoscope bending section	2.73(2.50)
Brush the suction channel in the insertion tube	2.73(3.00)
Clean brush with fingertips	2.55(2.50)
Depress pistons of each reusable part	2.64(2.50)
Attach the injection tube	2.64(2.50)
Test the potency of the disinfectant solution	2.64(2.00)
Verify that the proper connector is being used for the endoscope being reprocessed	3.45(3.50)
Attach the connector to the AER and endoscope	3.64(4.00)
Operate the AER according to the AER manufacturer's instructions	3.00(3.00)
Ensure the endoscope is soaked in the disinfectant solution according to the manufacturer's instructions for time and temperature	2.64(2.50)
Perform the terminal steps that AER does not perform (e.g. alcohol and air purge)	3.09(3.50)
Ensure that angulation locks are in the free position	2.91(3.00)
For endoscopes with flexible adjustment mechanism, set the insertion tube to maximum flexibility	3.00(3.00)

*The steps are listed in chronological order from the reprocessing procedure.

Ratings were found to be consistent across participants and errors were likely to happen in any of the major stages (e.g. leak testing, manual cleaning) of the reprocessing procedure. Of note, steps completed during high level disinfection (using an AER) tended to receive higher ratings of difficulty than other stages. This is interesting because this stage involves the most automation and requires the least manual work.

The interviews conducted with the expert reprocessing technicians provided rich qualitative data about the difficulties encountered in the endoscope reprocessing procedure. The notes recorded from the interviews were coded to determine the most frequent contributing factors to error or causes of difficulty as defined by the technicians (Table 2). The top three factors attributed to causing errors are prospective memory, lack of knowledge, and the design of the endoscope.

Prospective memory is synonymous with forgetting or skipping a step. Forgetting was cited as one of the biggest reasons users commit errors during endoscope reprocessing, implying that technicians are capable of completing all the steps, but they sometimes simply forget. For example, technicians must complete Leak Testing for every scope reprocessed. Technicians hook the endoscope up to an air compressor and place the scope under water to look for air bubbles escaping through damaged parts of the scope (Table 1). Often, technicians will forget to confirm that air is being emitted and thus have no idea if the air compressor is operational. This may result in failure to detect a leak (i.e. damage) to the endoscope.

Table 2. Most frequent contributing factors to error on difficult steps

Contributing Factor	Frequency
Prospective Memory	234
Lack of Knowledge	112
Product Design	63
Feedback	23
Training	38
Environment	20
Visibility	5

Lack of knowledge refers to when technicians commit errors because they don't know how to complete a step. For example, it was repeatedly mentioned that technicians experience difficulty when required to attach cleaning accessories to the endoscope. When an endoscope is placed into the AER for high level disinfection, there are various connectors that must be attached to the endoscope. However, many novice technicians don't know how these connectors attach to the endoscope and will use a process of "trial and error" until everything seems to fit. Having a connector inappropriately attached to the endoscope during high level disinfection can compromise the cleaning process leaving patients at risk for contamination.

Often, participants attributed lack of knowledge to errors that occur when technicians don't understand the importance of certain steps. For example, during leak testing, novice technicians often remember to observe the scope for 30 seconds while it is submersed under water. However, experts understand that one must also move the distal tip back and forth using hand controls to further check for damage. They understand the mechanics of the scope and thus have increased knowledge about the importance and reasoning behind specific steps.

During the interview, technicians commonly blamed the design of the endoscope for contributing to errors that occur in many difficult steps. For example, in one step of the manual cleaning task, technicians must brush two internal channels of the scope that reside within the same opening. One channel is cleaned by inserting the brush straight in the opening and the other channel can only be reached by inserting the brush at a 45 degree angle into the opening. This is a difficult step that is difficult to learn and can be easily skipped because the technicians cannot see the channels.

A gastrointestinal endoscope is large (almost 6 feet long), has long flexible tubes, and is awkward to handle for novice technicians. Experts reported that damage to the scope occurs often from coiling the tubes too tightly during sink cleaning, dropping the tubes on the floor, and closing them in the doors of the AER.

In addition to a general understanding of contributing factors to error, it is important to be able to link these factors to specific steps in the reprocessing procedure to identify general solutions. Figure 2 shows a Pathfinder network illustrating the relationships between the identified contributing factors and the steps rated highly difficult that tend to co-occur. In this case, co-occurrence was calculated using conditional probability. That is, the probability that errors will occur on a certain step, given that a contributing factor also occurs. For example, given that an error occurs on a brushing task, it's probable that this error is a result of prospective memory, thus there is a link between the two.

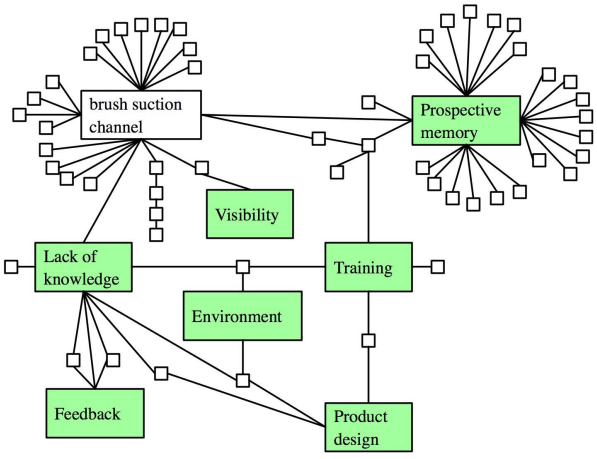

Figure 2. Pathfinder network of error prone steps and contributing factors

Prospective memory (forgetting) was the most frequently cited contributing factor to error and correspondingly tended to have the highest co-occurrence with difficult tasks in the reprocessing procedure. Figure 3 shows a close up of steps surrounding prospective memory from the overall Pathfinder network in Figure 2. This network illustrates that if an error occurs during brushing of the reusable parts, for example, it is highly likely that error is due to prospective memory.

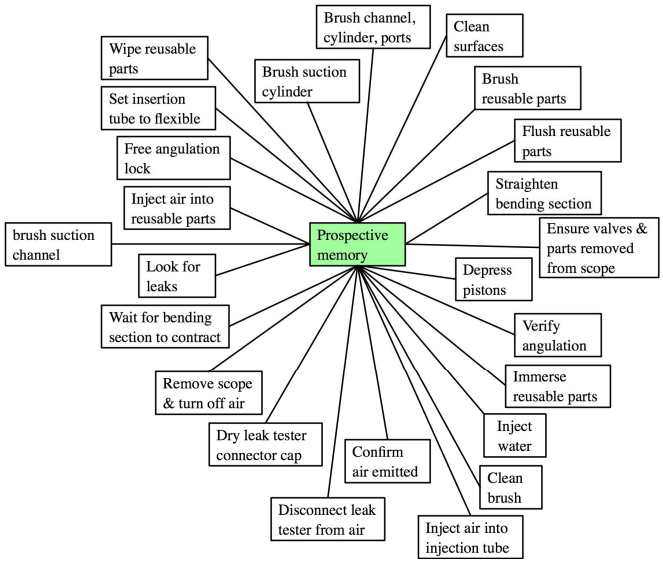

Figure 3. Close up of Pathfinder network and the steps that are related to errors due to prospective memory.

Discussion

The results from this study are consistent with the findings from other preliminary work examining human factors involved in endoscope reprocessing (Hildebrand et al 2010; Jolly et al 2011). Endoscope reprocessing is a difficult, complicated procedure that strains the cognitive resources of the user. It was found that forgetting and lack of knowledge tended to be the highest causes for novice technicians to commit errors during the reprocessing procedure. With over 200 plus steps to complete, while typically attending to multiple tasks, it's not surprising that technicians have difficulty in areas related to memory and knowledge.

Much literature to date recommends standardizing processes and equipment and increasing automation in order to eliminate human shortcomings (Ofstead, Wetzler, & Snyder, 2010). Some research has shown that automating processes (i.e. using AERs to complete additional stages) can result in performance equal to human users conducting manual cleaning (Alfa, Olson, & DeGagne, 2006). The problem is that without considering human factors, automation alone won't solve any problems. This study's ratings data implied that some of the most difficult and error-prone tasks surround interactions with the current AERs, implying that there may be additional usability problems with the AER equipment. In fact, of the 11 reprocessing

technicians interviewed there were 4 different types of AERs used. So, while automation may serve to standardize processes, manufacturers need to consider compatibility with the endoscopes, human factor principles, and the end users when designing these machines.

Above all, the main problem is that these endoscopes are not designed to facilitate cleaning. Issues with other components of reprocessing (i.e. complex instructions, confusing training, incompatible equipment, etc.) are a result of trying to accommodate a poorly designed device. While performance in patient care procedures is a main concern when designing elements of reusable medical devices, it is clear that manufacturers need to redesign endoscopes to make cleaning an easier and more usable process (Nelson, 2002; Seoane-Vazquez & Rodriguez-Monquio, 2008; Hildebrand et al 2010; Jolly et al 2011). During development, manufacturers must consider design elements that facilitate the needs of all end-users, doctors and reprocessing technicians alike. Cleaning reusable medical equipment is a critical task and must be a design priority, especially when errors in reprocessing can compromise patient safety and potentially lead to outbreaks, illness, and death.

Implementing changes to the design of a reusable medical device will take considerable time. In the meantime, the development and application of cognitive tools such as checklists and improved visual aids could provide support to reprocessing technicians and reduce the amount of errors due to prospective memory. The Pathfinder networks created from the interview data in this study can inform the design of cognitive tools to specifically address errors on a step-by-step basis.

Finally, the data from the ratings have highlighted areas where more serious usability problems may exist. It should be noted, however, that some technicians had a difficult time understanding the concept behind "rating the tasks' likelihood of difficulty". It was observed that some ratings tended to be unrepresentative of the qualitative data. For example, after assigning low ratings for some tasks, the interviewer would question the technician about that task and discovered the technician actually considered that task to be highly likely to induce difficulty and errors. Thus, technicians were often describing a higher number of errors and more serious incidents than they reflected in their ratings. This effect was seen in just under a third of the interviews. So, while these ratings point researchers in the right directions, the qualitative data from this study and the relationships revealed through the Pathfinder network analysis should direct future research in the development and applications of solutions.

Conclusion

Endoscope reprocessing is a complex and critical procedure. When completed incorrectly, patient safety is compromised as there are increased risks for outbreaks through cross-contamination. Human factors research has started to identify usability problems within the endoscope reprocessing procedure as well as design flaws in the endoscope itself. Future research in the field of human factors and reprocessing safety should focus on the necessary design elements of tools and cleaning procedures to better accommodate cognitive and perceptual limits of *all* end-users. By applying and validating solutions that can minimize the opportunities for errors to occur in endoscope reprocessing, these solutions can then be generalized to other types of reusable medical equipment.

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