The Human Factors of Reprocessing Reusable Medical Equipment

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The Human Factors of Reprocessing Reusable Medical Equipment

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OUTLINE

1. Introduction

Infection control is critical to patient safety. In the United States each year brings approximately two million healthcare-associated infections (HAIs) resulting in approximately 90,000 deaths (Stone, 2009). Single-use medical devices, which are used on one patient and then discarded, have helped reduce the number of HAIs. Unfortunately, not all devices can be made disposable. For example, endoscopes are complex devices which cost thousands of

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dollars, so making them disposable is prohibitively expensive. As a result, devices like endoscopes must be reprocessed, or cleaned and sterilized after each use. The problem is that many HAIs have been traced to errors in reprocessing procedures resulting in contaminated reusable devices. Failure to properly reprocess a medical device carries the risk of person-to-person transmission of viruses such as HIV, Hepatitis C, Hepatitis B, or other bacteria, as well as the transmission of environmental pathogens such as pseudomonas (Mehta et al., 2006; Nelson, 2003; Weber & Rutala, 2001).

Advances in medical science, minimally invasive surgical techniques, and diagnostic procedures have led to improved complex reusable medical devices, such as flexible video duodenoscopes and robotic surgical instruments, which require equally complex reprocessing procedures. Improving reprocessing is not only critical for reducing transmission of HAIs, but is imperative for maintaining trust in healthcare (i.e., if patients are afraid of acquiring infections they may be less likely to pursue preventative or needed medical treatments) and reducing healthcare costs. Healthcare facilities in the United States spend 9.8 billion dollars annually to treat the top five HAIs, and spend countless dollars more to address malpractice and wrongful death lawsuits associated with HAIs (AMA, 2013).

Hazard analyses and incident reports following reprocessing errors often cite use error in complying with manufacturer recommendations. However, design flaws are often disguised as human error or negligence in reprocessing of reusable devices. This chapter presents and discusses the human factors issues, best practices and guidelines for reprocessing reusable medical devices. Although endoscopes are used as an example, the information presented is applicable to all reusable medical devices.

2. Why is endoscope reprocessing a problem?

Endoscopes are not the only devices that are reprocessed, however they have become the poster child for the "issues in reprocessing" movement. Endoscope reprocessing has been listed as a top health technology hazard by the ECRI Institute over the last 10 years (ECRI, 2018). Recurring infectious outbreaks due to errors in endoscope reprocessing have been well publicized resulting in the scientific literature and the popular media asking "how clean are those reusable medical scopes" (Daly, 2017); and research shows that they are not clean enough. A 2018 study by Ofstead et al. studied endoscopes deemed "ready for use" in three separate hospitals. They found 71% tested positive for bacteria, indicating that the reprocessing procedure was not effective. The authors concluded that "unfortunately, there has been little to no improvement in this area over the past 10 years" (Ofstead et al., 2018).

2.1 What is reprocessing?

Reprocessing is the process which renders a clinically used device safe and ready for its intended reuse (AAMI ST91). The Spaulding classification system, developed in the 1960s, has been used to classify medical devices into categories based on their use and defines the level of cleaning, disinfection, and/or sterilization needed (Ramakrishna, 2002; AAMI ST91) based on the risk of infection involved with their reuse (Petersen et al., 2017). Using the Spaulding classification system, devices are identified as critical, semi-critical, or

non-critical as described below (Ramakrishna, 2002; AAMI ST91; FDA Reprocessing; Petersen et al., 2017):

- Critical devices penetrate skin or mucosa and carry a high risk of infection. Critical devices should be sterilized between uses. Examples include biopsy forceps.
- Semi-critical devices, such as endoscopes, do not penetrate intact mucous membranes and should be sterilized or high-level disinfected.
- Non-critical devices, such as blood pressure cuffs or patient carts, only contact intact skin and have very little risk of transmitting infection. Non-critical devices do not need to be sterilized and may be cleaned using low-level disinfection.

2.2 Endoscope reprocessing

Endoscopes, which fall into the semi-critical category, can be sensitive to heat, thus high-level disinfection is a commonly practiced method of reprocessing.

Endoscope reprocessing typically includes six tasks (Fig. 19.1).

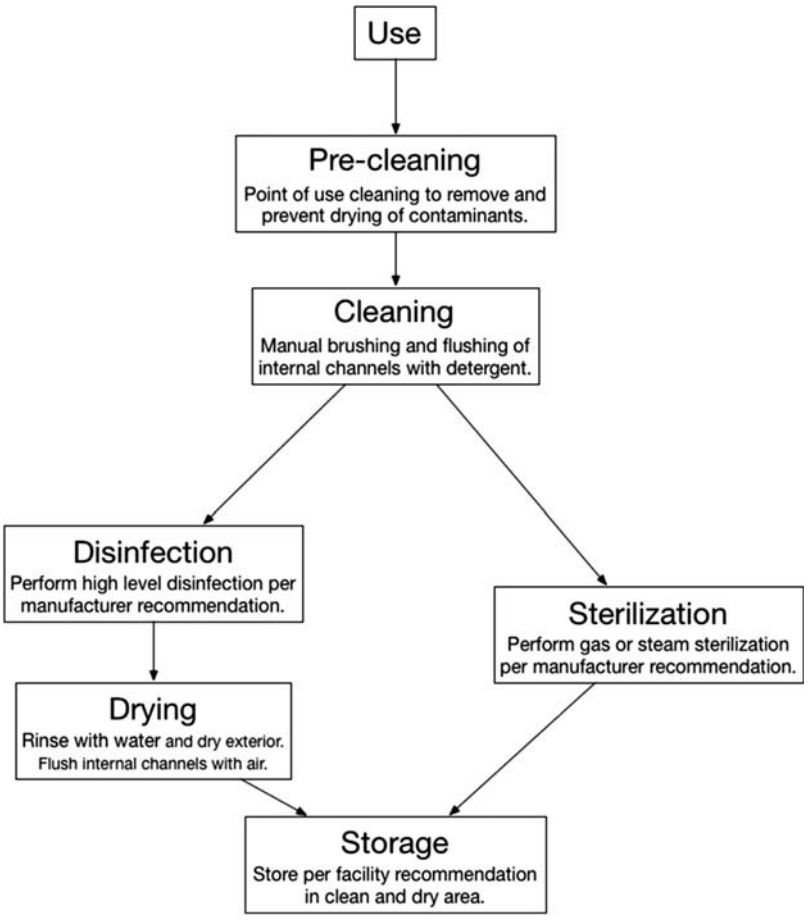

FIG. 19.1 Overview of the endoscope reprocessing procedure.

1. Precleaning or point of use cleaning: This happens immediately after a patient procedure, while the device is still in the procedure room. Its purpose is to remove gross contaminants from the endoscope before it dries by wiping the exterior and flushing the internal channels with water or detergent solution.
2. Leak Testing: This process detects damage in the endoscope prior to manual cleaning. Ensuring an endoscope is mechanically sound is necessary for the cleaning process to be effective.
3. Manual Cleaning: The endoscope is soaked in detergent solution and remaining gross contaminants are removed by manually and thoroughly wiping, brushing, flushing, and rinsing the exterior and internal channels of the device.
4. Disinfection or Sterilization: The choice to perform high-level disinfection or sterilization is made based on manufacturer recommendations. Whether or not an endoscope can be sterilized depends its materials and its ability to withstand different sterilization methods. High-level disinfection can be conducted manually, which involves soaking and flushing the endoscope with a germicidal agent. Alternatively, an automated endoscope reprocessor (AER), which performs that same steps in an automated machine, can be used.
5. Drying: After high-level disinfection, the endoscope is rinsed to remove residual cleaning agents. Then, endoscopes are flushed with forced air and typically flushed with alcohol to promote drying.
6. Storage: Proper handling during storage is important to ensure that contaminants are not reintroduced to the clean endoscope. Endoscopes should be hung vertically in clean, dry, well-ventilated, and humidity-free areas.

Depending on the type of endoscope and the manufacturer, the steps above can vary widely. Further, although not addressed in the steps above, endoscopes come equipped with disposable and reusable accessories. Technicians must identify and discard disposable accessories and reprocess the reusable accessories at the appropriate points in the reprocessing procedure.

3. Human factors issues in endoscope reprocessing

Reviews of existing literature on the causes of reprocessing errors usually places the blame on the human operator or "user" error. These analyses rarely take into account the interaction between the user and the device design, nor do they address the instructions-for-use (IFU), training, or environment (Hildebrand et al., 2010). Instead, most reports cite noncompliance with guidelines or reprocessing instructions as the primary culprit of errors (Nelson, 2003; Ofstead et al., 2010; Ramakrishna, 2002). Human factors practitioners, on the other hand, know that assigning blame to the user does nothing to mitigate problems and many problems classified as human errors are actually the result of poor device design.

The following sections discuss in detail three human factors issues that create difficulties for reprocessing technicians when interacting with reusable medical devices. Design principles and guidelines for these issues are also addressed. Understanding the challenges and difficulties users currently encounter help identify and develop solutions to minimize errors and improve reprocessing safety.

3.1 Device design

Put simply, ensuring safe reprocessing begins with the design of the device (AAMI TIR12). At present, unfortunately, medical device manufacturers focus foremost on preventing, diagnosing, monitoring and treating diseases and injuries (Malchesky, 1995). Reprocessing is at best an afterthought. Thus, it is no surprise that devices are difficult to clean. For example, some endoscopes have two internal channels accessed through the same port. During cleaning, it is difficult for users to distinguish the two channels and determine which one they are cleaning. Indeed, if distracted, users may skip cleaning one of these channels or accidently clean the same channel twice. One simple way to facilitate cleaning, is to add device labeling (e.g., text labels, color coding, etc.) related to reprocessing. Endoscopes already have multiple labels which serve as cues to clinicians during procedures, but there are rarely labels designed to cue reprocessing technicians.

A human centered design (HCD) process, including reprocessing technicians as a user group, could greatly reduce the likelihood of patient harm. HCD considers each device user early in the design process. In the case of reusable devices, reprocessing technicians should be considered as a primary user group. Manufacturers should learn about the needs, capabilities, limitations, and working environments of these technicians. General principles and guidelines for conducting and applying such user research are detailed in medical device guidance documents (AAMI HE75 2009; FDA, 2016; IEC/ISO 2015). Device design teams should contain at least one member who is responsible for ensuring the human factors of reprocessing. Further, reprocessing procedures should be evaluated through simulated-use usability studies with representative users as early as possible (AAMI TIR12).

Manufacturers should take care to design characteristics that have been identified as problematic for cleaning. The FDA (2016) has published lists of features that pose challenges for reprocessing, including hinges, shafts with lumens, elevator channels, porous materials, and ridges or grooves to name a few. Defining reprocessing design requirements during product development will help to avoid these design pitfalls.

In recent years, endoscope manufacturers have been under intense scrutiny for issues related to cleaning the forceps elevators on duodenoscopes. Despite following cleaning instructions appropriately, debris is often retained in these components on the devices. As a result, patients were exposed to infectious agents (FDA, 2018). Some manufacturers answered the call by designing single-use covers for the distal-end of the endoscope, to promote better cleaning (Fig. 19.2). Another manufacturer went a step further and designed a duodenoscope with a completely detachable and removable, single-use elevator

FIG. 19.2 Pentax recently released a duodenoscope with Cap H.D., a single-use, removable, cover for the distal end. This cover affords users the ability to more easily clean the forceps elevator, which is one of the key areas for potential recontamination. *Image source: Pentax Medical (2018).*

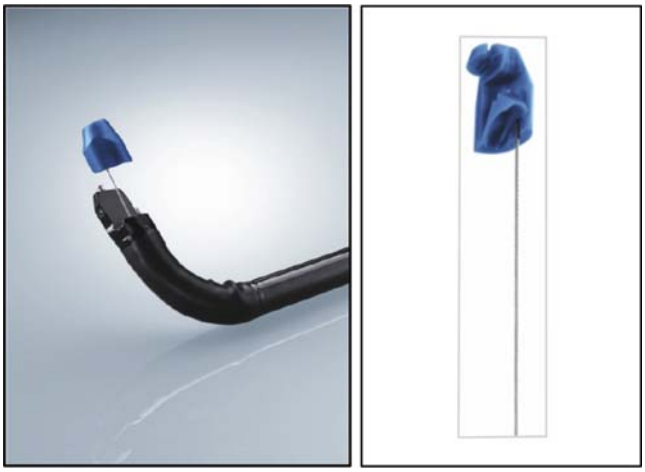

FIG. 19.3 KARL STORZ has designed a duodenoscope with an Albarran Module, a single-use (removable and disposable) elevator wire and forceps. This module importantly facilitates reprocessing by removing a component that is commonly difficult to clean. *Image courtesy of KARL STORZ.*

forceps module (Fig. 19.3). These types of innovations better support user performance in cleaning tasks and improve reprocessing safety.

Failing to design for reprocessing not only leads to complex devices, but also complex reprocessing procedures. For example, reprocessing a flexible endoscope can require over 200 individual steps and the use of over 20 different cleaning accessories (Hildebrand et al., 2010; Jolly et al., 2012). Moreover, facilities may reprocess as many as 250 endoscopes a week (Hildebrand et al. 2010, 2011; Ofstead et al., 2010). Taking an average, this could mean technicians are performing 10,000 steps per day. As human attention and working memory have limited capacities, each additional step in a cleaning process increases the likelihood of the scope being cleaned improperly due to steps being missed or completed incorrectly. Devising methods that provide immediate feedback and alert reprocessing technicians to failures could be critical for preventing potential errors. Further, methods for quickly evaluating the effectiveness of a reprocessing procedure, such as rapid cleaning monitors, could facilitate the recognition of improperly cleaned medical devices (Alfa, 2016).

3.2 Providing adequate instructions for use

In 2015, the FDA published guidance placing the responsibility for providing reprocessing instructions on the manufacturers of the reusable devices. Not only are manufacturers expected to provide instructions for reprocessing, but those instructions must be validated through usability testing to ensure that they can be understood by end users. (Alfa, 2016; FDA, 2015). Requiring manufacturers to provide useable instructions is important, however instructions should not be considered a primary means of mitigating potential harm as even the best designed instructions are unlikely to be used at the point of reprocessing. For example, it is difficult for users to reference a paper booklet in the wet environment of a reprocessing suite. Innovation beyond paper IFUs is needed to continue evolving and improving reprocessing practices. Design considerations for alternative methods of supporting and guiding users through reprocessing procedures could have substantial effects on user performance.

3.3 Training

Manufacturers commonly provide training via in-service sessions for the reprocessing staff. Regrettably, it is often challenging to assemble all of the reprocessing staff at once for training. Consequently, those technicians who attended training are left to train those who could not attend which may result in inconsistencies. Ultimately, healthcare facilities are responsible for ensuring that staff is trained to perform reprocessing as intended by the instruction and the manufacturer. Ideally, facilities have established practices for training technicians in reprocessing. Many incorporate an apprenticeship style approach where technicians learn from their predecessor. Unless training can be guaranteed by manufacturers across all facilities, it should not be relied upon as a method of mitigating harm when considering reprocessing in the device design process.

ANSI/AAMI ST91 provides guidance on implementing training and educational programs for flexible and semi-rigid endoscope processing in health care facilities. When developing training programs, whether it be an in-service, educational video, or visual aids, manufacturers should apply the same human factors approach to the design of instructional materials. Designers should ensure that information across all training mediums and the IFU are consistent and do not promote contradictory ideas. Finally, as with IFUs, manufacturers should seek to validate their training materials through use testing with representative users.

4. Case study

In 2009, the Department of Veterans Affairs (VA) mailed 10,000-plus letters to veterans, notifying them that they may have been exposed to or infected with bloodborne pathogens (including hepatitis B, hepatitis C, or HIV) due to improperly reprocessed endoscopes from procedures performed between 2003 and 2008 (ECRI, 2009, 2010). Most incident reports cited "reprocessing technicians inability to adhere to manufacturer cleaning instructions" (Hildebrand et al., 2010; Jolly, Hildebrand, & Branaghan, 2013; VA, 2009) (Fig. 19.4). In response, the VA National Center for Patient Safety funded a Patient Safety Center of Inquiry entitled the Center for Evaluation of Human Factors in Reprocessing Safety (CEHFRS). The goal of CEHFRS was to understand the issues involved in endoscope reprocessing from a human factors perspective. Not surprisingly, many, if not all, of the contributors to the problem listed above were identified quickly (Hildebrand et al., 2010).

One research effort identified and characterized challenges associated with IFUs for reprocessing. An initial usability study asked novice users to simulate endoscope reprocessing relying only on the reprocessing IFU and a supporting visual aid (i.e., manufacturer-provided poster). The results showed that none of the participants were able to reprocess the endoscope without error. Qualitative data analysis confirmed earlier research efforts (Hildebrand et al., 2010, 2011) and found that there were three major root causes: high memory demands; lack of visibility; and insufficient feedback (Jolly et al., 2012).

Norman (1993) stated, "The power of the unaided mind is highly overrated" (p. 43). Without external aids, our memory, thought, and reasoning are constrained. When well designed, external aids can complement our abilities, strengthen our mental powers, and help us overcome our own limits. However, in the case of reprocessing, poorly designed

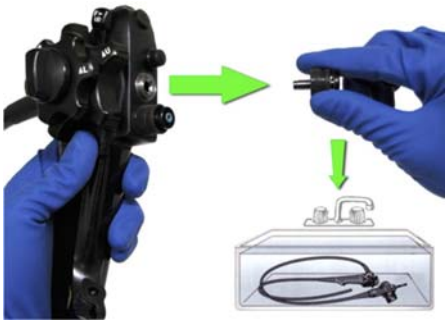

FIG. 19.4 Vision was supported by using consistent design and formatting conventions. The image above depicts green "action arrows" which were used to consistently inform the user of when and where to move a component of the endoscope. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.) *Image source: Jolly, Hildebrand, & Branaghan, 2013.*

support materials contributed to improperly cleaned endoscopes (Jolly et al., 2012). Accordingly, CEHFRS set out to redesign a cognitive aid, utilizing human factors design principles, that could effectively guide a user through the entire reprocessing procedure. During the design efforts, specific focus was given to address known usability issues by:

- Increasing visibility
- Reducing memory demands
- Providing adequate feedback

Visibility was supported by ensuring that visual aspects of the IFU were consistent throughout (Fig. 19.5). The same design elements (e.g. green arrows) were used repeatedly to indicate actions. Additionally, showing part tools with similar names up close, with clear pictures, made it easy to discriminate them.

Memory demands were addressed by reducing complexity in the instructions, while at the same time avoiding oversimplification. These improvements replaced the need to remember details by placing necessary knowledge in front of the user instead of requiring knowledge to be maintained in their memory. This was achieved by focusing on the following concepts:

- Orientation: The endoscope and tools were shown in a first person point of view to limit the need for mental rotation.

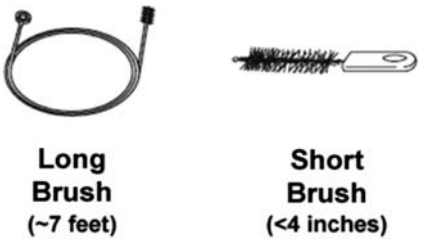

FIG. 19.5 Brushes with similar names are illustrated next to each other to assist the reader in discriminating between them. *Image source: Jolly et al. (2013).*

FIG. 19.6 This image depicts the attachment of a cleaning adapter to the endoscope. Visual and textual cues about how to physically manipulate the adapter (e.g., "push" and "slide") afford users the necessary steps to complete this task. *Image source: Jolly et al. (2013).*

- Visuals & Words: Text referring to a visual was placed in closeness, proximity to support understanding.
- Vocabulary: Text facilitated memory by removing similar sounding or confusing terms and limiting technical jargon (Fig. 19.6).

Feedback was incorporated by leveraging visual and auditory clues that users could rely on to ensure they completed a step correctly and completely (Fig. 19.7).

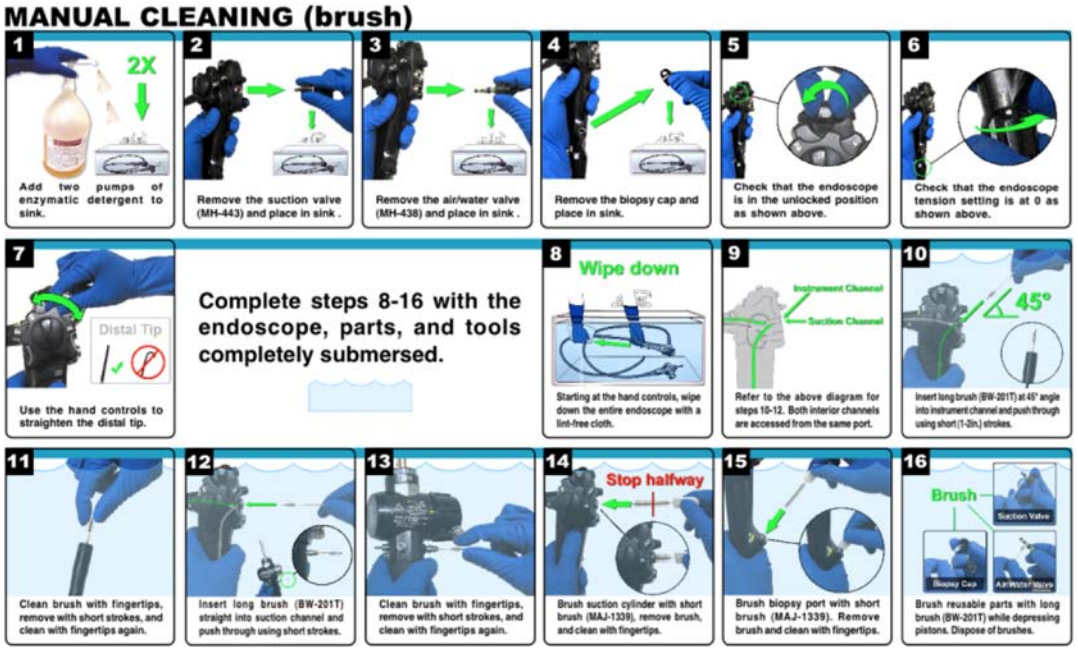

FIG. 19.7 Cognitive aid prototype for the "Manual Cleaning – Brushing" instructions provided to participants during usability testing of an endoscope reprocessing procedure. *Image source: Jollyet al. (2013).*

Below is an example of one cognitive aid prototype that was created utilizing the design goals and considerations above. In total, three cognitive aids were created to represent larger complex steps in the endoscope reprocessing procedure: leak testing, manual cleaning (brushing) and manual cleaning (flushing).

To assess the effectiveness of the cognitive aids, a comparative (between subjects) usability test was conducted in which novice participants simulated reprocessing relying only on the cognitive aids as a guide. The human factors-based cognitive aids were found to provide participants with significantly better support to perform reprocessing. Participants in the cognitive aid usability study completed more than 87% of the reprocessing tasks correctly, compared to less than 45% in an initial usability study. Participants using the cognitive aids were also significantly faster. For a detailed write-up of the process, evaluation, and findings see Jolly et al. (2013).

5. Summary

As the medical device industry proliferates and the need for complex reusable medical equipment increases, human factors in reprocessing needs to be at the forefront of the design process. If errors are made during reprocessing, devices may do more harm than good. Implementing human factors in the design of reusable medical equipment and reprocessing procedures will result in safer and more effective devices.

Key takeaways:

- Human factors issues for reprocessing should be considered early in the design process and should involve user research, iterative design, and evaluation through usability testing
- Design features that afford cleaning (easy-to-disassemble, disposable) and utilize labeling (color-coding, text, icons) to support reprocessing tasks should be implemented in to the design or reusable medical equipment

6. Further reading

Sources of information for applying human factors approach to reprocessing of reusable medical devices includes, but is not limited to, the following:

- AAMI TIR12: Designing, testing, and labeling reusable medical devices for reprocessing
- AAMI TIR55: Human factors engineering for processing medical devices
- AAMI HE75: Human factors engineering - Design of medical devices
- ANSI/AMMI ST91: Flexible and semi-rigid endoscope processing in health care facilities
- FDA guidance: Applying Human Factors and Usability Engineering to Medical Devices
- FDA guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- IEC/ISO TR 62366: Application of usability engineering to medical devices

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