Mandatory Accessibility & Usability Testing of Manufacturer’s Reprocessing Instructions for Reusable Medical Equipment (RME)

PROBLEM
Current reprocessing instructions are not accessible and not usable

Recent failures in reprocessing (cleaning and disinfecting) of medical equipment such as endoscopes have contributed to the spread of harmful bacterial and viral infections between patients. A possible cause for these failures is the reprocessing instructions currently available. Many instructions violate human factors principles and are unusable for use where they are needed most: at the point of reprocessing. Previous studies point toward electronic solutions that may provide utility. As a first step, the government agency as such as the FDA could utilize a systems approach to the creation and maintenance of these electronic instructions to decrease the preventable spread of harmful bacteria and disease.

PREVIOUS STUDIES

In an exploratory effort to understand the problems with reprocessing (specifically for endoscopes), we conducted a usability study that simulated a “worst-case” scenario where a user is asked to reprocess an endoscope with little or no previous training. In the experiment, participants were provided with only a brief orientation to the reprocessing procedure and allowed to utilize the manufacturer-provided instructions for the endoscope as they saw fit. The results were disappointing: none of 24 participants successfully reprocessed an endoscope, and on average, less than half of the procedure’s subtasks were completed without error.

To improve reprocessing performance, we created static visual aids (posters) designed to guide a novice user through the entire reprocessing procedure. We previously found that reprocessing errors typically arise from a lack of visibility of RME parts and tools, forgetting, and incomplete feedback cues. The visual aids incorporated human factors principles to mitigate these issues, and a best poster is able. Successful completion rate increased from 45% to 87% with the new aids. While this success confirms the effectiveness of the new visual aids, we still did not address the issue of accessibility. It is unrealistic to have posters on display for every RME reprocessing procedure at a given facility.

Accessibility + Usability = Safer Reprocessing

Accessibility: the degree in which a tool is available to be used by novices and expert reprocessing users.

Usability: the extent to which a tool can be used to achieve goals with effectiveness, efficiency, and satisfaction.

Moving toward an electronic solution

While we have shown that using static visual aids to meet the cognitive demands of reprocessing users is a more usable solution than current instructions, we have yet to address issues regarding accessibility. Our current study addresses this concern by changing the format of the aids from static posters to an interactive electronic guide (e-CheckList). Usability testing is an ongoing process, but initial findings show the e-CheckList to be at least as good, if not better, than the posters. Major benefits of the electronic guide are the increased accessibility of instructions with modes that vary by experience level, and the ability to store an infinite number of instructions at the point of use.

Instructions delivered electronically at the point of reprocessing is the first step to creating a viable system to increase adherence to procedures and ultimately improve patient safety.

How-to Guide for more usable instructions

The e-CheckList was created using a number of human factors and design principles. We have summarized them in the guide below titled, Incorporating Human Factors into Reprocessing Instructions: A How-to Guide. This concise guide provides manufacturers with evidence-based guidelines for creating clear, easy-to-use, safe instructions.

Mandatory Accessibility & Usability Testing

Currently, manufacturers are mandated to provide evidence showing reprocessing procedures result in RME that is safe for reuse on patients. However, these results are based on unrealistic scenarios that do not take the human reprocessor into account. Our research has shown that worst-case scenarios in which an unskilled technician must rely on instructions, that are neither accessible nor usable, can put patient safety at risk.

To account for this reality, governing agencies such as the FDA could mandate accessibility and usability testing of manufacturer’s reprocessing instructions as part of the approval process for RME. It would be easy to anticipate that no current instructions in our test would be “accessable” for all user types. Current manufacturer instructions are akin to short novels, printed in black and white, and non-waterproof. Our research has shown that worst-case scenarios in which an unskilled technician must rely on instructions that are neither accessible nor usable, can put patient safety at risk.

Supporting these findings are human factors-based design principles that seek to improve accessibility and reduce memory demands, providing instructions relevant to their level, and the ability to store an infinite number of instructions at the point of use.

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Make no mistake: this is not a small endeavor. However, a top-down, systems approach designed to positively affect the accessibility and usability of reprocessing instructions, will have the best chance for reducing the spread of harmful bacteria and disease between patients via RME that was reprocessed incorrectly.

Jonathan Jolly, Emily A. Hildebrand, & Russell J. Branaghan

Reference: