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Article *in* Human Factors and Ergonomics Society Annual Meeting Proceedings · September 2011

DOI: 10.1177/1071181311551166

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Human Factors Implications for Standard Operating Procedure Development and Usability in Reprocessing Safety

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The development of standard operating procedures (SOPs) in endoscope reprocessing is an oft-neglected task with vital implications. At present, there is little to no organizational standardization or facilitation to aid SOP development. After critical analysis of several SOPs from various hospital organizations, recommendations are put forth focusing on the application of guidelines within human factors and instructional design. These recommendations are anticipated to encourage better procedural development, promote organizational standardization, and facilitate usability for the end users.

Introduction

Ensuring that employees adhere to organizational standard operating procedures (SOPs) is a universal issue. In healthcare specifically, deviations from procedural requirements can result in errors leading to death or other serious adverse events. Of late, the adherence to reprocessing guidelines has come under the spotlight in the medical field (Moses & Lee, 2004). Reprocessing is a multi-stepped procedure that renders contaminated medical equipment safe for reuse (Muscarella, 2006).

Recently, reports of cross contamination due to improper cleaning of flexible gastrointestinal endoscopes have been prevalent in the media. While contamination due to gastrointestinal endoscopy is extremely rare, with an incidence rate of approximately 1 in 1.8 million procedures (Nelson et al., 2003), in the last two years, over 13,000 patients have been notified of potential exposure to infectious diseases (Pennsylvania, 2010).

Most of the literature surrounding infection control in endoscopy blames the user's inability to adhere to reprocessing guidelines as the culprit for infection transmission (Pennsylvania, 2010). However, bacteria has been shown to remain even after thorough cleaning in compliance with reprocessing guidelines (Seoane-Vasquez & Rodriguez-Monguio, 2008; cite).

Endoscopes are difficult to clean because of narrow channels and intricate parts (Rutala & Weber, 2004). The design of the endoscope itself, as well as the organization of content in SOPs, has been found to violate many human factors design principles; resulting in potential usability problems for end users (Hildebrand et al, 2010). The current design of flexible endoscopes is acceptable for functionality in patient procedures; however, it is poorly designed for cleaning and maintainability. It will be difficult to write cleaning instructions for a device that is designed without cleaning as a priority. This suggests that reprocessing errors are likely not the user's fault, but are a result of the interaction between the operator and the product, as well as the manufacturer's cleaning instructions, training curriculum, and standard operating procedures. In this case, redesigning the endoscopes to facilitate cleaning would be the ideal option (Nelson, 2002; Hildebrand, 2010), but doing so will require large amounts of time, money, and resources. In the meantime, redesigning the procedural instructions is a more cost effective change to implement.

This paper will explore how we can improve the current standard operating procedures in endoscope reprocessing and answer the following questions: What are the current problems with SOPs? How can they be improved to facilitate compliance and increase usability?

Methods

We utilized multiple methods to explore the problems involved in SOP development. To start, we requested the SOPs for the same gastrointestinal flexible endoscope from several Level 1 hospitals. We compared these SOPs against one another and with the manufacturer's reprocessing instructions, looking for variances in consistency, content, and overall organization.

Next, we interviewed several SOP writers, reprocessing technicians, and experts in instructional design. The SOP writers answered questions regarding their approach to writing SOPs, their opinions on what constitutes effective SOPs, and the kinds of challenges they face in writing them. Reprocessing technicians described their daily interactions with SOPs, what they like or dislike about SOPs, and what they would change about them. We consulted instructional design experts on the current issues related to reprocessing SOPs and asked for their opinions on how to improve SOP development to increase usability and compliance.

Lastly, we reviewed the instructional design literature and human factors design principles concerning composition of instructional environments.

Results and Discussion

Problems:

Analysis of the SOPs revealed a lack of organizational standards which negatively affected the appearance and content. Appearance issues such as improper and inconsistent margins, numbering, chronicling, sectioning, and font stylization rendered some of the SOPs visually and instructionally incoherent. Content issues varied from either having too much or too little content. For example, all of the Level 1SOPs that we collected covered the same device; yet, one SOP was more than twice the length compared to the others. Further, there was a consistent mismatch between the SOPs and the manufacturer's reprocessing instructions. Facility SOPs either provided an overwhelming amount of detail and information or lacked critical elements necessary to successfully complete the reprocessing procedure. Additional content errors were apparent in the inappropriate use of advanced vocabulary, inconsistent sentence patterns, and variable placement of warnings and cautions. These results highlight fundamental errors in the instructional development process.

The SOP writer interviews, revealed them to be overloaded and directionless. Producing SOPs is an unremitting process on account of the exhaustive attention and knowledge each device and its subsequent updates require. Most SOP writers have other primary obligations within their respective organizations that supersede their SOP writing demands. These conditions are often compounded by the influence of differing areas with differing agendas.

SOP writers have to take into account input not only from manufacturer's instructions, but must also satisfy the needs of technicians, health care inspectors, facility executives, and device manufacturers. These dissimilar backgrounds typically offer idiosyncratic perspectives, sometimes at the cost of clarity and job performance (Jackson & Schuler, 1985; Adobar, 2006). For instance, during an interview, an SOP writer acknowledged the low educational backgrounds commonly found amongst technicians. As a result, the SOP writer stressed appropriation of SOP content based upon an 8th grade reading level. However, when questioned about the inclusion of words too advanced for such a reading level, the SOP writer cited manufacturer wording and fear of legal liability. This dissonance in SOP content decision-making is a reflection of a lack of organizational standardization. As a result, the SOP end users may be provided with SOPs that are difficult to interpret.

It is evident that SOP writers have a difficult task of synthesizing information while also taking care of concurrent obligations. The task becomes even more difficult due to a lack of resources (e.g. access to updated manufacturer's instructions), and access to peer communication. Without such resources, SOP writers expressed feelings of seclusion in translating information for SOP production.

In its very nature, interpretation through a singular perspective biases content; SOP writers are not immune to personal predispositions. With varying backgrounds from military, nursing, or logistics, and varying levels of technical writing ability, the writers' interpretations of what is appropriate is often influenced by different mental frameworks.

Collectively, these issues result in SOPs that are misguided and deficient in procedural execution. When personnel are faced with excessive cognitive loads, job performance suffers (Sweller, 1988; Paas & van Merrienboer, 1994a; Merrienboer & Sweller, 2005). Interviewed technicians were similarly overwhelmed as a result of each SOP's inability to effectively instruct. In each facility, SOPs were sparingly used by technicians.

In sum, we have isolated SOP writers' lack of direction on how to translate and coordinate necessary information as the primary source of SOP issues. As such we have compiled human factors design principles, the instructional design experts' recommendations and the knowledge acquired from the instructional design literature review to provide guidance for developing effective SOPs.

Recommendations:

Two basic ingredients are needed to write an effective instructional device: time and information (Robinson, 2009). Rewriting a document over time produces superior results (Hayes & Flower, 1986). SOP writers need to find time to produce several drafts of the SOPs and pilot test each finished draft with end users to evaluate its effectiveness. It is imperative to use empirical data found through these tests to validate the usability of the SOPs. The actual content of these drafts is equally important.

The following recommendations will focus on improving the quality and quantity of information SOP writers' are able to gather. These recommendations are expected to facilitate the standardization of SOP production by improving the translation of quality information and increasing the coordination of such information.

Translating Quality Information. To improve translation, we borrow design principles from human factors and instructional design. It is critical to apply these principles first and foremost with a user-centric focus. Human factors and instructional design principles are rooted in creating an environment calibrated towards user capabilities (Wickens et al., 2004; Roytek, 2010; Robinson, 2009). End users are vital in the development process since their inclusion can aid knowledge and skill retention (Wickens et al., 2004). Thus, reprocessing technicians should be involved in the development and writing stages of SOPs as they are the ones carrying out the reprocessing task.

In addition to a user-centric focus, SOP writers should always be consistent (Wickens et al., 2004; Parrish, 2007; Robinson, 2009). This means that the forthcoming appearance and content recommendations should be repeated in a consistent manner across and within all SOPs. Reprocessing technicians should be able to predict the location of specific elements and information for immediate access.

How information is presented is important because aesthetics heighten an observer's feeling of experience immersion (Parrish, 2007). To improve SOP appearance, we recommend the use of instructional design strategies such as sectioning and arrangement, as well as human factors' strategies such as attention to proximity.

Sectioning can help alleviate the cognitive strain associated with information overload (Miller, 1956; Koedinger & Anderson, 1990; Robinson, 2009; Perlman et al., 2010). When applied to endoscope reprocessing, SOPs can be sectioned into distinct phases based upon the major component tasks: precleaning, leak testing, manual cleaning, high level disinfection or sterilization, drying, and storage.

Instructional material should be logically arranged to facilitate the users' cognitive resources (Parrish, 2007; Robinson, 2009). This is fundamentally imperative to reprocessing endoscopes since generating a clean scope is dependent upon chronological and consistent execution of procedures. Content should be effectively outlined and stylistic devices such as fonts and margins should be fitting for an instructional environment (Robinson, 2009). An example of proper arrangement includes placing no more than seven warnings and other cautionary pieces of information at the beginning of a process section (Robinson, 2009). More than this and users are apt to either ignore or forget the cautionary information. Additionally, steps that need to be carried out chronologically should be outlined using sequential numbers and pieces of information should be outlined using bullets.

Related information should be arranged within close proximity to each other (Wickens et al., 2004). Any pictures corresponding to instructions should be placed adjacent to its related piece of text. Reprocessing procedures should have preceding, current, and proceeding steps in proximal and chronological order. Minimizing cognitive strain through these arrangement strategies will facilitate technicians' attention to the present task, inherently reducing errors.

To improve SOP content, writers should incorporate instructional design principles such as contextualizing, active involvement of the user and human factors principles such as making content meaningful and easy to visualize (Parrish, 2007). Context and active involvement of the user serve to stimulate the user during instruction, effectively giving the information meaning and pace (Parrish, 2007). SOP writers can address these guidelines in endoscope reprocessing by including the purpose for the technicians' task, specifically where they apply within the device's functionality and why their task is vital. This gives purpose to the technicians' task. Additionally, SOP writers should begin action-oriented sentences with an action verb. For example instead of writing, "the connector cap should be attached," SOP writers should write, "Attach connector cap." Doing so incorporates the user as the principal operator during procedural tasks (Robinson, 2009).

For instructions to be meaningful it must be significant to the mental models of the end user (Wickens et al., 2004). When SOP writers use vocabulary that is foreign to technicians, instructions are rendered meaningless. We recommend that SOP writers only use words, icons, acronyms, etc. that are within technicians' mental models.

Content should be easy to visualize. This allows the user to predict device function (Wickens et al., 2004). For example, SOPs should visually detail what technicians should see during leak testing, providing contextual feedback to the user. This principle can also be accomplished through use of pictures.

Furthermore, these propositions should also be applied to warnings. A good warning begins with an appropriate signal word (e.g. Warning, Caution, Notice, etc.), the nature and severity of the hazard, how this hazard can be avoided, and what happens if not avoided.

Manipulating SOP content through these propositions should allow writers to engage technicians

in an environment that avoids human errors due to inattention, frustration, and confusion.

Coordinating Quality Information. Interviews with instructional design experts led to the conclusion that there must be an increase in organizational communication, collaboration, and standardization. Increasing organizational communication is effective in reducing the perceived cognitive load on job learning effectiveness (Lin, 2010). As follows, the use of novel technologies such as online communication tools and document standardization are recommended. Applying such technologies should increase the coordination of access to quality information and development of usable SOPs.

Instructional design suggests that better instructional writing comes from intra- and inter-organizational collaboration achieved through use of novel technologies (Tolusa et al., 2008; Abdous & He, 2008; Murry & Murry, 2000). Research in business and academia uncovers several methods that can be modified towards realizing this goal.

Technology can be beneficial towards increasing access to and coordination of quality information. Interactive devices and communication technologies foster richer collaborations and are effective in sharing resources and tools (Tolusa et al., 2008). We recommend the use of a standardized, widely accessible, online SOP template. Research in the field of academia has found that use of such technologies in production of instructional material results in high producer satisfaction, increased collaboration and communication, simplification of expectations to the end user (Abdous & He, 2008), and effectively includes the end user's needs (Murry & Murry, 2000). Additionally, the ease of accessibility to a standardized template significantly reduces production time (Abdous & He, 2008; Murry & Murry, 2000).

Though SOP production is rarely associated with academia, both employ instructional devices to serve as a foundation for users to successfully navigate towards a final goal (Gagne et al., 2005). Whether it is to facilitate students' course progress or aid technicians in reprocessing an endoscope, the instructions are created to have a procedural pace with a means to an end.

Accordingly, when composing SOPs, organizations should encourage intra- and inter-collaboration through technological means. Implementing a widely accessible template would promote the exchange of ideas and content, while also offering some form of SOP standardization. Additionally, creating an online forum with access to standardized templates could increase communication and collaboration amongst SOP writers, executives, inspectors, and most importantly, technicians. Interaction within an organization has been shown to ease excessive mental effort during job performance (Putnam, 1995). With access to a larger quantity of rich information, SOP writers would be able to effectively maximize time and efficiency.

Conclusions

SOPs should be more than just a procedural document. Like an instruction manual alongside a device, SOPs should be a solid embodiment of an organization's principles as well as a useful reference and guide to the user (Driscoll, 1994; Robinson, 2009). The suggestions in this paper, such as proper translation of the resulting information and use of a standardized template fostering communication and collaboration are simple to implement in a short time period. When 80,000 hospital patients find themselves ill and 30,000 dead due to improper procedural performance by hospital employees, the importance of functional SOPs suddenly becomes apparent (Aizenman, 2010).

SOPs are critical to proper device operation; endoscope reprocessing is no exception. Though these recommendations and design principles are well established in the field of human factors and instructional design, further testing will be necessary to validate the outcomes for SOP development in endoscope reprocessing and other reprocessing activities. Based on the successes of these principles in other fields, it is expected that the implementation of these recommendations will result in a more robust assurance of patient health and wellness due to increased safety in reprocessing procedures.

Implications for further study within the field of reprocessing are vast. We expect SOP production and technician understanding to be accelerated, a decrease in technician reprocessing error, avoidance of costly malpractice litigation, and a more robust assurance of patient health and wellness. After all, hospitals are a company selling health and wellness. Markedly, a company is only as good as its product and its product is only as good as its usability.

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Funding for this work was provided by the VA National Center for Patient Safety. This work was also supported with resources and the use of facilities at the Phoenix Veteran's Affairs Health Care System. The contents of this article do not represent the views of the Department of Veterans Affairs or the United States Government.