

Infection Control in Endoscopic Retrograde Cholangiopancreatography: A Human Factors Perspective

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ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY-RELATED INFECTIONS

Endoscopic retrograde cholangiopancreatography (ERCP) is a common procedure, with over 700,000 performed annually in the United States (1). The unique design of duodenoscopes is critical to performing ERCP because it affords direct visualization of (and ability to manipulate) the duodenal papillae. However, this design also makes duodenoscopes among the most difficult devices to disinfect (2). Duodenoscope-related infectious outbreaks have occurred worldwide (3–5) and have increasingly involved multidrug-resistant organisms (3,6,7). Consequently, there is an increased global awareness of these potential events, along with higher standards for reprocessing, documentation, and reporting (8,9). Duodenoscope-related outbreaks are life-threatening, with potential 1-month mortality rates of over 20% (10). Apart from the problematic design of traditional duodenoscopes, there are several other factors potentially contributing to outbreaks, including errors in manual cleansing or automated high-level disinfection, issues with scope maintenance or repair, and general lack of knowledge of this threat among practitioners and staff (11). Preventing duodenoscope-related outbreaks therefore requires careful consideration of multiple influences, including human factors. This brief review is intended to inform relevant stakeholders of the importance of ERCP-related infections and to consider potential outbreaks from a systems perspective, aiming toward optimizing future preventive interventions.

HUMAN FACTORS AND ERCP

The science of human factors applies principles from psychology, physiology, and engineering toward optimizing a process or analyzing adverse incidents (12). Human factors science is increasingly being used within healthcare domains, given its broad importance (13). ERCP is a complex procedure, suggesting that there are several system-related components that contribute to a level of unpredictability in patient outcomes (14). Pre- and post-

procedural equipment-related factors are of particular interest, and given the variables involved, a human factors analysis of ERCP-related infection is of substantial value. We conducted a thematic analysis using data from a focus group comprising 2 endoscopists and 2 nurses, in addition to a full literature review of human factors methodology and ERCP-related infections.

IDENTIFYING AND CONTROLLING RISK IN ERCP

There are customarily several controls in place within a health-care system that collectively prevent the incidence of undesirable events. The process of successful high-level disinfection after ERCP involves multiple system components that are intended to work synchronously. The goal is an efficient and thorough decontamination process that allows duodenoscopes to be available for safe use on future patients. Failure of this process at any stage has the ability to lead to residual duodenoscope contamination, which can result in transmission to future patients. Residual contamination, therefore, is the first step in a cascade of events that can ultimately lead to an ERCP-related infectious outbreak.

Bowtie analysis is a well-described method of identifying system risks and managing them by analyzing related threats, barriers, and consequences (15,16). A bowtie analysis summarizing duodenoscope reprocessing can be found in Figure 1, created using inputs from our thematic analysis and literature review. There are several elements to this diagram (15). The centerpiece is the hazard—an activity or occurrence with the potential to result in harm—in our case, the ERCP procedure. The hazard is capable of leading to an undesirable “top event”—in this case, residual contamination. On the left of the diagram, there are threats (represented by red rectangles), which, left unchecked by barriers (represented by green rectangles), will lead to the top event. Barriers are also present on the right-hand side of the diagram, being necessary to prevent the top event from leading to significant consequences (represented by thick red rectangles). Degradation factors (represented by orange ovals) are aspects that can prevent barriers from fulfilling their task of acting as controls (15).

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ANALYSIS OF A HYPOTHETICAL OUTBREAK

Having described the theoretical environment for risk, it is valuable to explore a hypothetical ERCP-related outbreak using modern accident models. One such model is an AcciMap (17), a technique for accident analysis that explicitly assesses the causes that contribute to its occurrence within a complex system. Essentially, an AcciMap is a graphical portrayal of causal interactions between factors that have the potential to contribute to an undesirable outcome. An ultimate goal of AcciMaps is to identify at-risk areas in which to target future interventions to improve safety (18). An AcciMap analysis of a hypothetical ERCP-related outbreak is presented in Figure 2, created using inputs from our thematic analysis and literature review.

Several external circumstances relate to ERCP outbreaks, such as financial and political circumstances defining an institution’s baseline ability to purchase potentially safer equipment. Equally important are antibiotic practice patterns contributing to the rise of resistant organisms (19). The internal environment includes factors such as high procedural volumes contributing to an expectation for efficient turnover, which can increase errors or breaches in manual disinfection protocols before automated

reprocessing. Also contributing is an unenlightened workplace environment centered around blame and repercussions, rather than systems-based solutions (20). This facilitates the development of consequences such as complaints and litigation.

Duodenoscope design is arguably the most important prerequisite for ERCP-related infection. Other equipment considerations include maintenance of reprocessing equipment, proper signage describing manual cleansing protocols, and proper labeling in scope storage cupboards to prevent expired scope usage. Also crucial is the duodenoscope’s lifespan and undetected mechanical issues requiring repair (21). A failure in any of these factors can lead to the use of a contaminated scope. Reprocessing duodenoscopes also requires highly trained personnel and efficient communication. Time pressures and scheduling also factor into alertness, productivity, and minimizing errors.

FUTURE STEPS

The purpose of this exercise is to find tangible points at which to intervene and to develop strategies by which to do so. First, knowledge translation is paramount, and evidence-based methods

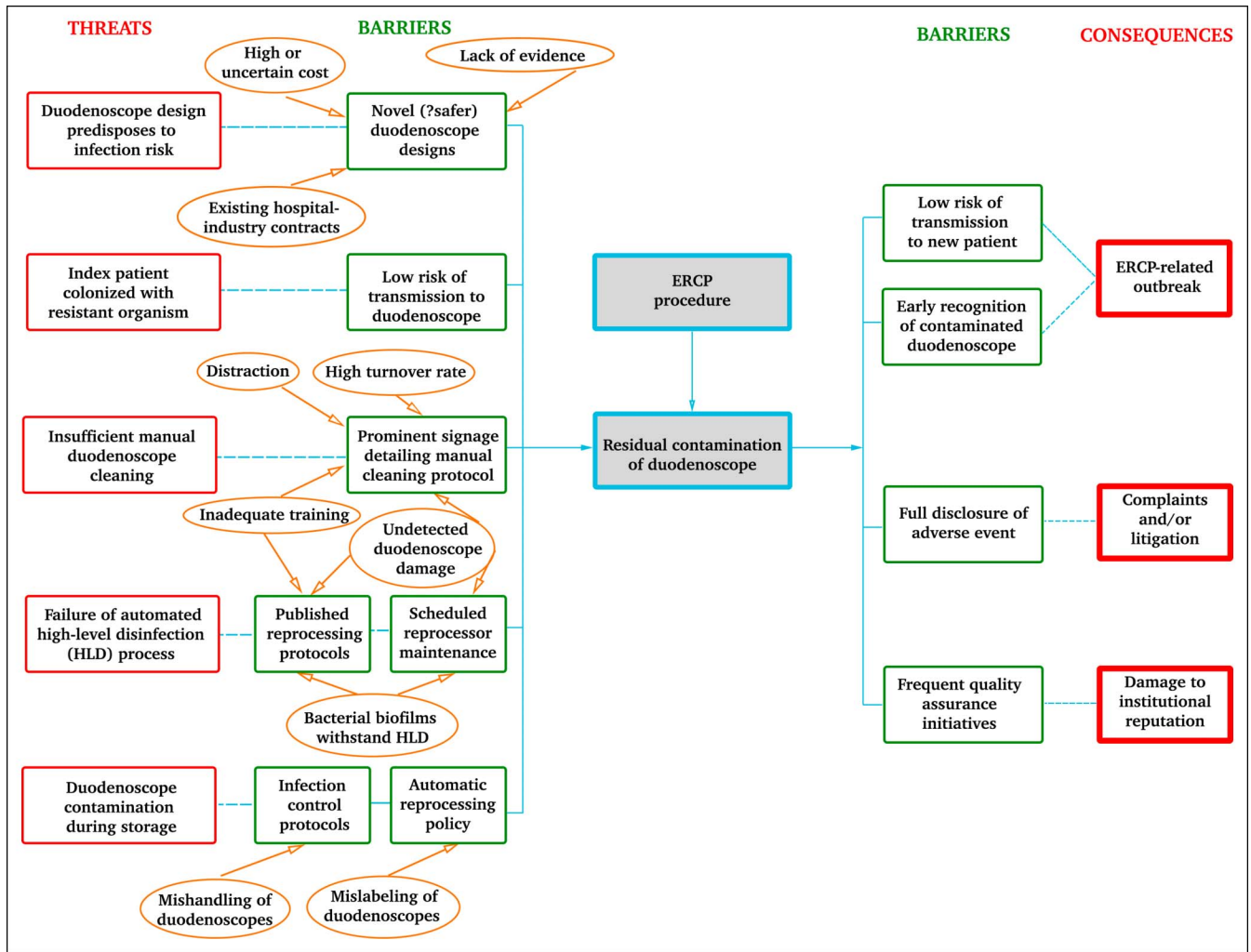


Figure 1. Bowtie analysis of duodenoscope reprocessing (ref. [15]). ERCP, endoscopic retrograde cholangiopancreatography; HLD, high-level disinfection. (Adaptations are themselves works protected by copyright. So in order to publish this adaptation, authorization must be obtained both from the owner of the copyright in the original work and from the owner of copyright in the translation or adaptation.)

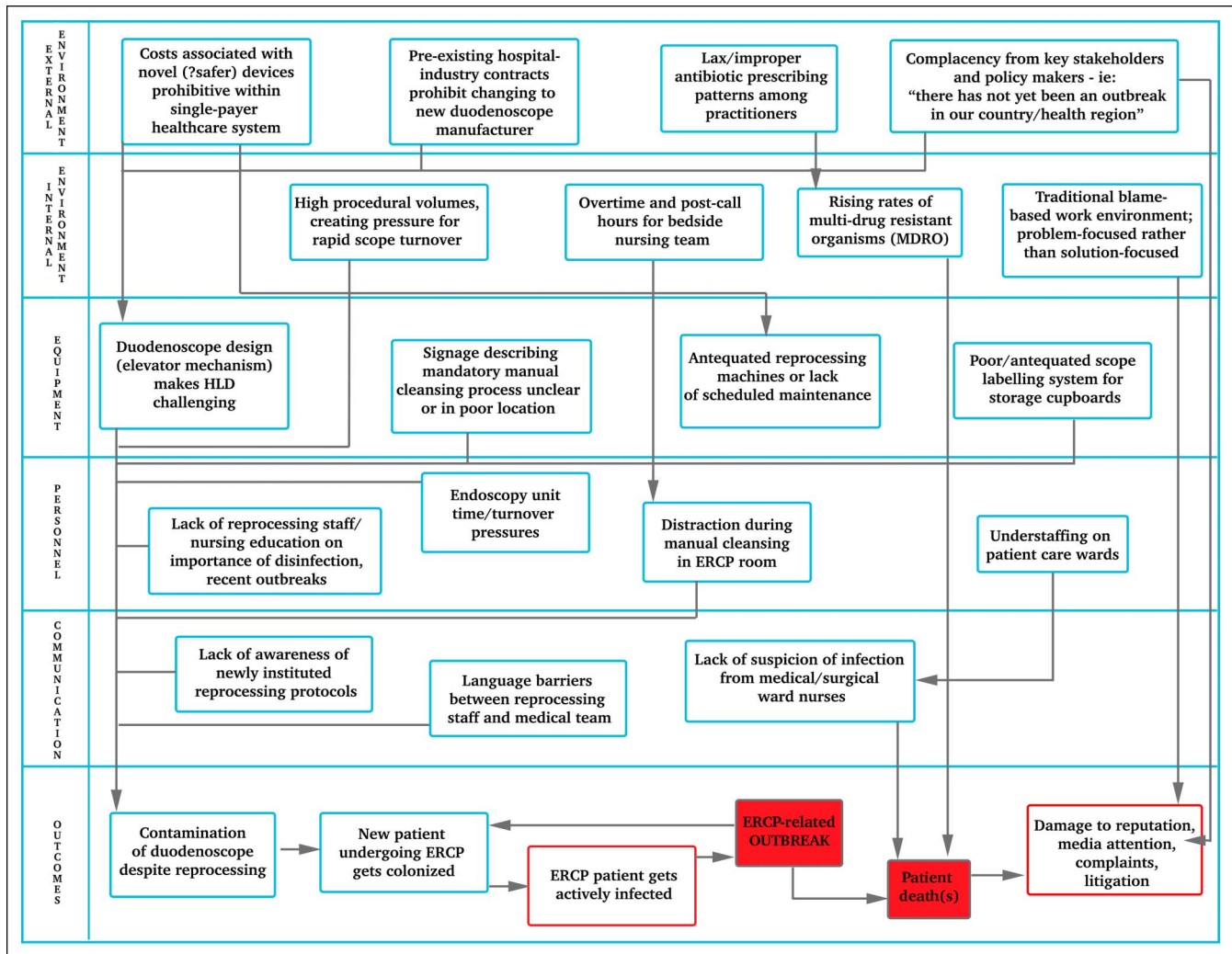


Figure 2. AcciMap analysis of a hypothetical ERCP-related outbreak (ref. [17]). ERCP, endoscopic retrograde cholangiopancreatography; HLD, high-level disinfection. (Adaptations are themselves works protected by copyright. So in order to publish this adaptation, authorization must be obtained both from the owner of the copyright in the original work and from the owner of copyright in the translation or adaptation.)

of achieving this should be considered (22). Education of endoscopists, nurses, and reprocessing staff is critical, not only for day-to-day operations but also to advise on potential outbreaks and their risk factors. These efforts should take place in an attempt to change culture in both endoscopy and reprocessing units (23). Second, reprocessing protocols should be closely reviewed at institutions performing ERCP to assess for potential weaknesses placing patients at risk (24). Third, the implementation of mandatory routine institutional microbiologic audits should be considered to ascertain persistent contamination rates and local infection patterns. Fourth, proactive routine duodenoscope servicing should be performed to assess for damage that would otherwise go undetected (21). Finally, several promising novel duodenoscope designs have emerged; however, high-quality data on infection reduction and technical efficacy are lacking, meaning that researchers must make this important area a research priority in the near future (25).

CONFLICTS OF INTEREST

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