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High-level endoscope disinfection processes in emerging economies: financial impact of manual process versus automated endoscope reprocessing☆

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SUMMARY

Background: The use of flexible endoscopes is growing rapidly around the world. Dominant approaches to high-level disinfection among resource-constrained countries include fully manual cleaning and disinfection and the use of automated endoscope reprocessors (AERs). Suboptimal reprocessing at any step can potentially lead to contamination, with consequences to patients and healthcare systems.

Aim: To compare the potential results of guideline-recommended AERs to manual disinfection along three dimensions — productivity, need for endoscope repair, and infection transmission risk in India, China, and Russia.

Methods: Financial modelling using data from peer-reviewed published literature and country-specific market research.

Findings: In countries where revenue can be gained through productivity improvements, conversion to automated reprocessing has a positive direct impact on financial performance, paying back the capital investment within 14 months in China and seven months in Russia. In India, AER-generated savings and revenue offset nearly all of the additional operating costs needed to support automated reprocessing.

Conclusion: Among endoscopy facilities in India and China, current survey-reported practices in endoscope reprocessing using manual soaking may place patients at risk of exposure to pathogens leading to infections. Conversion from manual soak to use of AERs, as recommended by the World Gastroenterology Organization, may generate cost and revenue offsets that could produce direct financial gains for some endoscopy units in Russia and China.

Introduction

The use of flexible endoscopes is growing rapidly around the world. These costly and delicate instruments must be reprocessed following each procedure to achieve high-level disinfection, ensuring that patients are not exposed to a previous patient's pathogens. There are no reported cases of endoscope-transmitted infection in which endoscope reprocessing was performed in accordance with professional and manufacturers' guidelines.

Missing or rushing through key steps is a common problem in both industrialized and developing countries. Contaminated endoscopes have been linked to more outbreaks of hospital-acquired infection than any other medical device.[1]

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Improper reprocessing can lead to potential contamination at any stage of the process. Inadequate cleaning can leave excess bio-material on an endoscope, even after multiple reprocessings.[2] In one study of endoscope cleaning practices, 22% of endoscopes still had infective viruses present after disinfection.[3] If the endoscope is not soaked in high-level disinfectant for a sufficient period of time, hard-to-kill pathogens such as bacterial spores, mycobacteria, fungi, *Staphylococcus aureus*, and viruses such as human immunodeficiency virus (HIV) and hepatitis B (HBV) may survive.[4] If the disinfectant solution is not thoroughly rinsed from the scope after soaking, patients can experience the acute discomfort of chemical colitis.[5,6] Rutala *et al.* found that residual glutaraldehyde levels were up to 25 times higher after manual cleaning compared with automated disinfection.[1]

In many countries, the predominant approach to endoscope reprocessing is a fully manual process (manual soak) in which the disinfection step involves soaking in glutaraldehyde. Variability in manual reprocessing has been associated with suboptimal results. The World Gastroenterology Organisation (WGO) recommends the use of an automatic endoscope reprocessor (AER) where sufficient resources are available, as the most extensive of a cascade of options for improvement.[4] However, in resource-limited countries, assessment of WGO recommendations requires a thorough understanding of associated capital and operating costs compared against quality improvements and other possible benefits. Accordingly, we sought to model the financial impact of converting from manual soak in GA to an AER, exemplified by the Endoclens-NSX™ (Advanced Sterilization Products, Irvine, CA, USA), an AER using orthophthalaldehyde (OPA), in endoscopy facilities in Russia, India, and China. An estimate of the potential exposure to infection under practices reported by endoscopy personnel in these countries was calculated.

Methods

Sources for this analysis include professional standards, especially those of the WGO; clinical literature accessed through searches on Medline and Embase; standards and source documentation of the US Centers for Disease Control and Prevention (CDC); internet searches for country-specific data in English; questionnaires and inquiries of field staff; and results of ASP-funded market research by Junicon® (San Ramon, CA, USA). The market research consisted of 50 minute interviews conducted in 2010 with hospital endoscopy laboratories (25 per country), sampled with quotas for hospital size and reprocessing method.[7]

Our analysis compares potential effects of changing from manual soaking in glutaraldehyde to an AER along three dimensions: productivity (including both revenue gain and labour savings), endoscope repair (including direct repair cost and revenue gain), and infection rates (number of patients potentially exposed under current practices and implications for national health systems).

Endoscope reprocessing using manual soak in glutaraldehyde requires six main steps: (1) bedside pre-cleaning, (2) cleaning and brushing, (3) rinsing, (4) soaking in glutaraldehyde, (5) final rinsing, and (6) drying with air and/or alcohol.[4] Time spent on these steps was estimated separately for each country from research results. Survey respondents performing manual soak processes in each target country were asked for the number of minutes from the end of one procedure until the scope is ready for the next patient (total scope turnaround time). Subtracting the average soaking time in glutaraldehyde, reported on the same survey, provided the minutes available for all other reprocessing tasks, from which a minimal allowance of 3.4 min, calculated from literature sources, was allocated for final rinsing/drying.[8]

With an AER, the soaking, final rinsing and drying steps are all done in the machine, which also performs supplemental cleaning and rinsing of the scope. The manufacturer-recommended soaking time for OPA in an AER unit is five min, versus the WGO-recommended 20 min soak in glutaraldehyde with manual reprocessing. The same first three steps are performed in both processes; our estimates assume that personnel will perform those tasks at current levels of time and diligence with or without an AER. The manufacturer-specified cycle time of 19 min for Endoclens-NSX™ was assumed for the AER.

The productivity impact of an AER was estimated using an operational model that compared average endoscopy procedure time (plus a one min allowance for moving patients) to the operational flow of scope reprocessing under both systems. Endoscopy procedure time was estimated using the survey-reported mix of endoscopy procedure types in each country and procedure times reported in the literature (22 min for colonoscopy and 36 min for bronchoscopy) or by Medicare (20 min for gastroscopy).[2,9] We assumed a simplified model of two primary working scopes per procedure room — meaning that a scope from one patient procedure is reprocessed while a second patient procedure is performed; delays occur if the first scope is not ready by completion of the second procedure. The value of reducing these delays is realized by adding procedures to the daily schedule, potentially increasing revenues.

Results

Productivity

Average survey-reported scope turnaround time under manual soak ranged from 21.5 min in India to 47.5 min in Russia (Table I).[7] In India, where scope turnaround under manual soak (21.5 min) is less than estimated endoscopy procedure time (22.6 min), no systematic delay occurs; AER adoption yields no additional procedures or revenue gain. In Russia, scope turnaround time (47.5 min) is significantly longer than the average endoscopy procedure (24.4 min). In China, scope turnaround time is slightly longer than the average procedure time (26.2 vs 22.3 min), resulting in an average per-procedure delay of 2.5 min.

Scope turnaround time using an AER with OPA is faster than with manual soak. The resulting reduction in procedure room delays means that an average of 3.9 procedures could be added per day in Russia (3.9 min per procedure reduction in delay × 24.5 procedures per day/24.4 min per procedure), resulting in an annual revenue gain of (US)$47,353 (3.9 procedures/day × five operational days/week × 52 weeks/year × $47 per procedure).[3] Similarly, we estimate revenue gains of $67,485 in China. Direct labour savings were minimal, yielding estimated total annual savings of $111, $622, $513 in India, Russia, and China, respectively.