Journal of Hospital Infection 86 (2014) 250–254

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

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

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ARTICLE INFO

Article history:
Received 14 August 2013
Accepted 28 January 2014
Available online 22 February 2014

Keywords:
Automatic endoscope reprocessor
Decontamination
Disinfection
Endoscopes
Infection control

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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0195-6701/$ — see front matter
http://dx.doi.org/10.1016/j.jhin.2014.01.007

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.

Table I
Survey-reported average total turnaround time per endoscope and soak time by country, and estimated allocation of time among reprocessing tasks based on survey-reported soak time and studies

Variable	Reprocessing time (min)		
	India	Russia	China
Total scope turnaround time, mean (95% CI)[a]	21.5 (19.7, 23.0)	47.5 (43.5, 51.5)	26.2 (22.0, 30.4)
Soak time in glutaraldehyde[a]	20.0	20.0	20.0
Reprocessing tasks other than soaking (time available for cleaning, rinsing/drying) (calculated)	1.5	27.5	6.2
Manual cleaning and rinsing before soaking (calculated)	0.8	24.1	3.1
Final rinse and dry after soaking[b]	0.8	3.4	3.1

CI, confidence interval.
[a] Survey-reported value.
[b] Value calculated from literature, subject to limitation that time for cleaning, soaking and rinsing cannot exceed total scope turnaround time.

Repairs

The potential to reduce the cost of endoscope repairs with an AER derives from an estimated 34% reduction in the amount of manual handling during reprocessing, resulting in fewer opportunities for the scope to be inadvertently mishandled. From a survey of 43 centres, Kirkpatrick *et al*. found that 18% of endoscope damage occurs during reprocessing.[10] We estimated savings in repair costs at 34% × 18% × the facility's annual cost of preventable repairs, which studies indicate are 58% more costly than unavoidable repairs.[11,12] Individual repairs vary widely in cost, depending on the nature of the damage, whereas field personnel consistently reported an average cost per repair of $5,000. With literature indicating that 64% of endoscope repairs are preventable, we estimated that preventable repairs (58% more costly) would average $5,763, whereas unavoidable ones would average $3,643.[5] Estimated annual repair costs under current manual soak also considered the mix of procedures and the literature-reported average number of uses between repairs (94.5 to 98.4 uses per repair) for bronchoscopes and other endoscopes.[5–7]

Additionally, when a scope is sent out for unplanned repairs, procedures may have to be cancelled. We assumed five days per unplanned repair (at five procedures per day) until other patients could be scheduled for procedures using a different type of scope or a loaned scope. Thus, assuming an average revenue of $47 per procedure, the average annual gain in revenue expected to result from a reduction in avoidable endoscope repairs was $2,772 in India (2.4 repairs avoided per year), $4,101 in Russia (3.5 repairs), and $8,649 in China (7.4 repairs).

Infection exposure risk

The WGO recommends the use of AERs, which supplement manual cleaning with additional washing and rinsing to reduce the risk of disease transmission via endoscopes.[2] Since the risk of transmitting disease via a poorly cleaned endoscope cannot be studied prospectively in humans, we relied on an animal study. In a study used by the US CDC to establish endoscope reprocessing standards, endoscopes used on HBV-infected ducks were soaked in glutaraldehyde for 5, 10, and 20 min, with no prior manual cleaning.[13] Healthy ducks were injected with material from the soaked but uncleaned endoscopes, resulting in HBV infection rates of 90%, 70%, and 6%, respectively; suggesting that the 20 min glutaraldehyde soak reported by most surveyed endoscopy centres could leave transmissible viruses on 6% of scopes if no cleaning was performed first.

When all recommended reprocessing standards are followed, the risk of disease transmission from an endoscope is virtually non-existent — all reported cases have been associated with a breach of these protocols or defective equipment.[14] Alfa *et al*. reported that well-trained personnel performing manual cleaning in accordance with manufacturers' recommendations and professional standards required 14 min (bronchoscopes) to 25 min (side-viewing duodenoscopes) for the cleaning tasks; we assumed a mid-point of 19 min as the time required for the manual cleaning portion of reprocessing.[15] We are aware of no systematic observational study of actual endoscope reprocessing practices in India, China, and Russia. Accordingly, we estimated manual cleaning time in these countries using survey-reported average scope turnaround and soaking times (Table I). For the final rinse and dry, we allowed a conservative 3.4 min, consistent with observed practice in a study by Ofstead *et al*. that did not assess the adequacy of the rinsing performed.[4] We compared the remaining minutes, assumed to be spent in manual cleaning, to the 19 min time for cleaning to professional standards, in order to estimate the percentage of required cleaning actually performed. Estimated manual cleaning times in India (0.8 min) and China (3.1 min), as a percentage of optimal cleaning efforts were 4% in India, 16% in China, and 123% in Russia. Total endoscope turnaround time in Russia (an average of 47.5 min) allows enough time for manual cleaning to professional standards, especially if performed by experienced personnel.

As previously noted, studies have shown that no scopes soaked for 20 min in glutaraldehyde after being fully cleaned to professional standards, and 6% of scopes not cleaned at all, retain transmissible pathogens. We assumed a linear relationship between the percentage of optimal cleaning effort and the amount of this remaining risk eliminated. Thus, as shown in

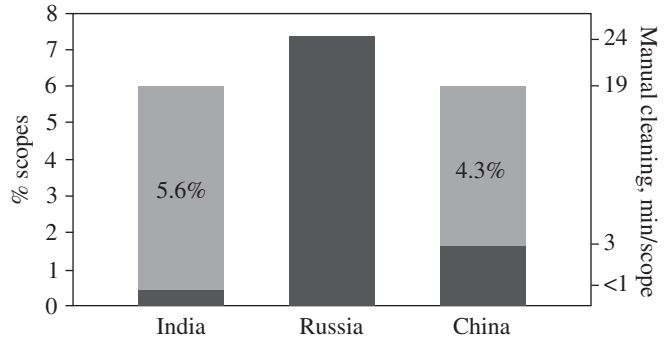

Figure 1. Endoscope cleaning effort and estimated proportion of endoscopes that could still retain transmissible pathogen. [▪], % scopes on which pathogen, if present, could remain after reprocessing (left axis); [■], minutes of manual cleaning per scope (right axis). Time needed for cleaning to standard: 19 min.

Figure 1, under self-reported operational practices for manual soak reprocessing, 4.3% of reprocessed endoscopes in China and 5.6% in India could still retain transmissible pathogens.

Furthermore, pathogens may be present on a poorly cleaned scope only if a prior patient was infected. Accordingly, the absolute risk of an endoscopy patient being exposed to a pathogen was estimated for India and China for three viral diseases (all of which can be transmitted by endoscope) as the product of the percentage of scopes that could retain transmissible pathogens and the societal prevalence of the disease.[16–22] As shown in Table II, we estimate that current practices in an average endoscopy facility in China could result in the exposure of between 41 and 103 patients to HBV, 17 patients to hepatitis C (HCV) and one patient to HIV, annually. If one patient is infected for each incident of disease exposure, patients survive at least 1–10 years and receive treatment at an annual cost for HBV of $13 in India and $2 116 in China,[21–25] the estimated cumulative national impact over 10 years would be roughly $25 million in India and $170 billion in China.[23–26]

Table II
Estimated number of endoscopy patients exposed to HBV, HCV and HIV in three countries, based on self-reported practices for reprocessing using manual soak in glutaraldehyde and country-specific ranges of disease prevalence

Variable	India	Russia	China
Annual procedure volume per GI unit	3840	5880	11,904
Estimated % of infected scopes retaining transmissible pathogens	5.6%	0	4.3%
Disease prevalence			
HBV – low	2.0%	2.0%	8.0%
HBV – high	10.0%	7.0%	20.0%
HCV	1.3%	2.0%	3.2%
HIV	0.3%	1.0%	0.1%
% of manually reprocessed scopes estimated to retain viable pathogen			
HBV – low	0.11%	0	0.35%
HBV – high	0.56%	0	0.87%
HCV	0.07%	0	0.14%
HIV	0.02%	0	0
Potential number of patients exposed annually in an average GI unit under current reprocessing practices			
HBV – low	4	–	41
HBV – high	21	–	103
HCV	3	–	17
HIV	1	–	1

HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; GI, gastrointestinal.

Capital investment and operating costs

The cost of acquiring and operating the AER unit must also be taken into consideration. We assumed a capital investment per endoscopy facility for the AER(s) and initial service contracts of $22,750 in India, $27,887 in Russia, and $60,000 in China (two units). The incremental increase in supply costs with an AER includes all manufacturer-recommended filter changes, pre-filter (where required), Cidex® OPA Solution, detergent and test strips used per manufacturer standards, versus manual soak costs based on current reported usage and estimated product costs. The resulting increase in supply costs is shown in Table III.

Table III
Summary of cost increases, savings and revenue gains (US$) with an Endoclens-NSX™ automatic endoscope reprocessor (AER) compared with manual soak in glutaraldehyde

	India	Russia	China
Added cost of AER supplies			
Savings (added cost) on supplies – fluids, filters and strips	$(17,141)	$(23,216)	$(66,808)
Cost savings generated by use of an AER			
Repairs. Potential reduction in cost of repairs	$13,737	$20,319	$42,858
Labour time. Nurse/tech time savings from reduction in hands-on tasks	$111	$622	$513
Subtotal: cost savings	$13,847	$20,941	$43,371
Revenue gains generated by use of an AER			
Repairs. Potential reduction in frequency of scopes out for repair	$2,772	$4,101	$8,649
Productivity. Processing time efficiency gain (loss)	–	$47,353	$67,485
Subtotal: revenue increase (decrease)	$2,772	$51,453	$76,135
Subtotal: cost savings and revenue enhancements	$16,620	$72,394	$119,506
Total: grand total change in annual operating margin	$(522)	$49,179	$52,698
Capital investment: AER unit(s) + initial service contract	$22,750	$27,887	$60,000
Payback period (years)	NA	0.57	1.14
Payback period (months)		7	14

NA, not applicable.

Financial summary

Estimated annual costs and financial benefits of the AER unit versus manual soak in glutaraldehyde are summarized in Table III. In countries where revenue can be gained through productivity improvements, adopting the AER has positive direct impact on financial performance, achieving payback of 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 for the AER.

Discussion

This study has several limitations. The results presented here use country-wide averages, which may not be representative of individual facilities. Analysis of current practices is based on self-reported data, and self-reported glutaraldehyde soaking time of 20 min (as is widely recommended) would leave little time for cleaning and rinsing if total scope turnaround barely exceeded 20 min, as was reported. Additionally, immunization rates would affect the risk of actual disease transmission and this has not been accounted for in our estimates. Water quality testing and regular training to ensure staff competency are recommended for both AER use and manual reprocessing; differential costs for water and energy use, staff training, or water quality testing have not been assessed or included, and may be higher if an AER is adopted.

In developing economies, the decision to invest in capital equipment is made within a context of limited resources and competing demands. Assessments of operational costs versus operational benefits and disease prevention are rarely seen in the literature, in part due to the paucity of country-specific comparative data. As a first step in an open assessment of automated endoscope reprocessing in three emerging economies, we examined the costs and potential benefits along three dimensions of efficiency and outcomes. Among endoscopy facilities in India and China, survey results on endoscope reprocessing using manual soak suggest practices that are not in compliance with manufacturer instructions and WGO guidelines, and could place patients at risk of exposure to infections. Conversion from manual soak to use of an AER as recommended by the WGO may generate cost and revenue offsets that could result in direct financial gains for some endoscopy units in Russia and China.

Conflict of interest statement
None declared.

Funding source
Funding for this study was provided by Advanced Sterilization Products.

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